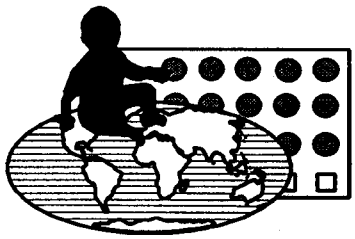


Newborn Screening Quality Assurance Program

PERFORMANCE EVALUATION AND QUALITY CONTROL

Summary Report
Inborn Errors of Metabolism

Volume 18

January 2001

INTRODUCTION

Newborn screening for detection of treatable, inherited metabolic diseases is a major public health responsibility. Effective screening of newborns using dried-blood spot (DBS) specimens collected at birth, combined with follow-up diagnostic studies and treatment, helps prevent mental retardation and premature death. These blood specimens are routinely collected from more than 95% of all newborns in the United States; state public health laboratories or their associated laboratories routinely screen DBS specimens for inborn errors of metabolism and other disorders that require intervention. For more than 22 years, the Centers for Disease Control and Prevention (CDC) with its cosponsor, the Association of Public Health Laboratories, has conducted research on materials development and assisted laboratories with quality assurance (QA) for these DBS screening tests. Most laboratories that test DBS specimens participate voluntarily in our Newborn Screening Quality Assurance Program. The QA services primarily support newborn screening tests performed by state laboratories; however, we also accept other laboratories and international participants into the QA program. Currently, the program provides QA services for congenital hypothyroidism, phenylketonuria, galactosemia, congenital adrenal hyperplasia, maple syrup urine disease, homocystinuria, biotinidase deficiency, and hemoglobinopathies.

The QA program consists of two DBS distribution components, quality control (QC) and performance evaluation (PE). The QC program enables laboratories to achieve high levels of technical proficiency and continuity that transcend changes in commercial assay reagents while maintaining the high-volume specimen throughput that is required. The external QC materials, which are intended to supplement the participants' method- or kit-control materials, allow participants to monitor the long-term stability of their assays. The PE program provides laboratories with quarterly panels of blind-coded DBS specimens and gives each laboratory an independent external assessment of its performance. DBS materials for QC and PE are certified for homogeneity, accuracy, stability, and suitability for all kits manufactured by different commercial sources.

In 2000, 207 laboratories were active program participants; of these, 152 participated in the PE component and 162 in the QC part. On page 23, a bar chart shows the distribution by analyte for all participating laboratories. For biotinidase, galactose-1-phosphate uridyltransferase (GALT), and hemoglobins, QC materials are not distributed because of the limited availability of appropriate blood sources.

PERFORMANCE EVALUATION

All PE panels contained five blind-coded 100-µL DBS specimens. Specimens in the PE panels contained either endogenous levels or were enriched with predetermined levels of thyroxine (T_4), thyroid-stimulating hormone (TSH), phenylalanine (Phe), total galactose (Gal), 17 α-hydroxyprogesterone (17-OHP), leucine (Leu), and methionine (Met). Special separate panels for biotinidase deficiency and for GALT deficiency were prepared with purchased blood from donors with enzyme deficiencies. Specimens for the hemoglobinopathies panel were prepared from umbilical cord blood.

Specimen sets were packaged in a zip-close metallized plastic bag with desiccant, instructions for analysis, and data-report forms. We prepared and distributed quarterly reports of all results that had been

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
and the
Association of Public Health Laboratories

received by the cutoff dates. In this annual report, charts for quantitative data on pages 6-19 and tables for qualitative assessments on pages 20-22 summarize the data from all PE reports received during 2000. Only the qualitative assessments are reported for the PE surveys for sickle cell disorders and other hemoglobinopathies, for the biotinidase deficiency PE surveys, and for the pilot PE surveys for GALT deficiency. Presumptive clinical classifications (qualitative assessments) of some specimens may differ by participant because of specific clinical assessment practices. If participants provided us with their cutoff values (summarized in the chart on page 23), we applied these cutoffs in our final appraisal of the error judgment. The errors for qualitative assessments in the PE component are split into misclassifications and transcription errors. A bar chart on page 22 shows the number of errors reported by disorder in 2000 for all qualitative assessments by domestic laboratories and by foreign laboratories.

QUALITY CONTROL

For QC shipments of T_4, TSH, Phe, Gal, 17-OHP, Leu, and Met, each lot contained a different analyte concentration. To ensure that a laboratory received representative sheets of the production batch, we used a random number table to select the set of sheets for each laboratory. The QC materials were distributed semiannually and included the blood-spot sheets, instructions for storage and analysis, and data report forms. Data from five analytic runs of each lot and shipment were compiled in the midyear and annual summary reports that were distributed to each participant. Intervals between runs were not the same for all laboratories because each participant's reported data cover a different time span.

The reported QC data are summarized in tables on pages 26-45, which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the standard deviations (SD) by kit or analytic method. In addition, we used a weighted linear regression analysis to examine the comparability by method of reported versus enriched concentrations. Linear regressions (Y-intercept and slope) were calculated by method for all analytic values within an analyte QC series. Values outside the 99% confidence limits (outliers) were excluded from the calculations. A summary table of the different matrices used for calibrators (dose-response indicators) by analyte is provided on page 46.

FILTER PAPER

The paper disk punched to aliquot DBS specimens is a volumetric measurement and requires a degree of uniformity among and within production lots. As part of the QA program, we used an isotopic method[1] developed at CDC to evaluate and compare different lots of filter paper. Mean counts per minute of added isotopic-labeled T_4 within a 1/8-inch disk were equated with the serum volume of the disks from the dried whole blood specimens. In comparing production lots, we used statistical analyses of the counting data to determine values for homogeneity and serum absorption of the disks. To avoid the variability contributed by uncontrolled red blood cell (RBC) lysis, we initially used lysed-cell whole blood for variance studies with filter paper. The results of later studies have indicated that RBC lysis during the process is not sufficient to contribute substantially to the variance; however, the mean serum volume per disk is different with intact-cell blood. For historical reference and for maintaining uniformity of testing on all the paper production lots, we have continued using the lysed-cell procedure. We also measure performance with intact-cell preparations. The standardized acceptable volumes per 1/8-inch disk are 1.30 ± 0.19 µL (mean value and 95% confidence interval) for lysed-cell blood and 1.54 ± 0.17 µL for intact-cell blood.[1]

The serum-absorbance volumes of 18 lots of Grade 903 filter paper (Schleicher & Schuell, Keene, NH) determined from lysed-RBC blood and for 8 lots determined from intact-RBC blood, are shown in chronological order on page 25. For W001, the most recent production lot of Grade 903 filter paper, we found the mean serum-absorbance volume to be 1.30 µL for a 1/8-inch disk for lysed-cell blood and 1.40 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot W001 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within the acceptable limits).

In 1996, the Food and Drug Administration (FDA) approved the filter paper, BFC180, produced by Whatman Inc. (Fairfield, NJ) as a blood collection device. The BFC180 was evaluated by CDC according to the criteria previously described.[1] The serum-absorbance volumes for seven lots of BFC180 filter paper determined from lysed-RBC blood and determined from intact-RBC blood, are shown in chronological order on page 24. For 0465, the most recent production lot of BFC180 filter paper, we found the mean serum-absorbance volume to be 1.27 µL for a 1/8-inch disk for lysed-cell blood and 1.50 µL per 1/8-inch disk for intact-cell blood. Each mean value is within the acceptable range for the matrix used. Lot 0465 was homogeneous (i.e., the measured within-spot, within-sheet, and among-sheets variances were within the acceptable limits).

INFORMATION RELATED TO DATA ANALYSIS

Filter paper lots used in the CDC production of QC and PE specimens distributed in 2000 were W941, W961, and W981 of Grade 903. All filter paper lots were analyzed for agreement with the evaluation parameters according to the NCCLS approved standard.[1]

Charts and graphs show the enriched concentrations of all PE specimens and QC lots as well as the summarized quantitative data. The total concentration of each specimen or lot was equal to the sum of the enriched concentration and the endogenous concentration (nonenriched). For T_4 PE specimens, the CDC assayed values were reported because of differences in the blood sources used for DBS production. Some specimens were enriched above the endogenous T_4 concentration, and some were enriched with T_4 after T_4 depletion of the base serum. All DBS specimens in the PE surveys and QC production lots were prepared from whole blood of 55% hematocrit. Purified analytes or natural donor blood, except for TSH, which used the Second International Reference Preparation (80/558), were used for all enrichments. For galactosemia, enrichments were made with galactose, galactose-1-phosphate, or both so that both free galactose (galactose alone) and total galactose (free galactose plus galactose present as galactose-1- phosphate) could be measured. All reported analytic values outside the 99% confidence limits and PE values associated with transcription errors were excluded from the summaries of quantitative results.

For obtaining data on the QC materials, we estimated the method response to endogenous materials by performing weighted linear regression analyses for mean-reported concentrations versus enriched concentrations. We then extrapolated the regression lines to the Y-axis to obtain an estimate of the observed endogenous analyte concentration for each method category. These estimates are reliable when 1) enrichments are accurate, 2) the analytic method gives a linear response across the range of the measurements, and 3) the slopes for regression lines are approximately equal to one.

DISCUSSION

Each year, with the extensive cooperation of manufacturers (Schleicher & Schuell and Whatman) of filter papers approved by the FDA for blood collection, we have conducted routine evaluations of new lots and compared new lots with previous lots. The criteria for acceptable performance are the approved limits established in the NCCLS standard.[1] Each manufacturer is also expected to establish its own testing program using the NCCLS standard and make available to the user its certification data for each distributed lot of paper. The independent evaluations by CDC are an impartial and voluntary service offered as a function of our quality assurance program and do not constitute preferential endorsement of any product over other specimen collection papers approved by the FDA. The table on page 46 presents the different sources of calibrator matrices that were used to calculate reported results. Overall, DBS calibrators on Grade 903 are the most prevalent matrix. Liquid matrices were used for 14% of reported Phe data and for approximately 20% of Leu and Met data. (As an illustration of the impact of paper on measurements, see TSH data on page 46.) Participants reported consistently lower overall mean TSH levels for TSH QC materials on Grade 903 filter paper when using DBS calibrators spotted on Grade 903 than when using DBS calibrators spotted on Grade 2992 filter papers. About 2½ times as many laboratories used calibrators on Grade 903 as used calibrators on Grade 2992. The TSH data reported by a few laboratories were deleted from the data base because data were reported in unacceptable units (i.e., whole blood). Even with our staff's persistent effort, the reporting of TSH values in the wrong units continues to be a problem.

The PE quantitative results (pages 6-19) are grouped by kit or method to illustrate any method-related differences in analyte recoveries. Because some of the pools in a routine PE survey represent a unique donor specimen, differences in endogenous materials in the donor specimens may influence method-related differences. The T_4 and TSH results showed a reasonably consistent performance among the different methods, with two methods showing slightly higher values for some T_4 specimens and one TSH method showing a high bias for concentrations equal to or greater than 65 µIU/mL. Overall, the TSH comparability among methods appears better than reported last year. For Phe, the reported results show high variability among the methods. Overall, the recoveries for Phe were good when both enrichment and endogenous concentrations were weighted in the assessment. The among-method comparisons of mean values appear reasonable for Gal and 17-OHP. Two methods for Gal showed high recoveries for the 17 mg/dL and higher enriched specimens.

For the qualitative assessments (presumptive clinical classifications) in the PE surveys (pages 20-22), tran-

Annual Report Dedicated to Rudy Hormuth 1923-2000

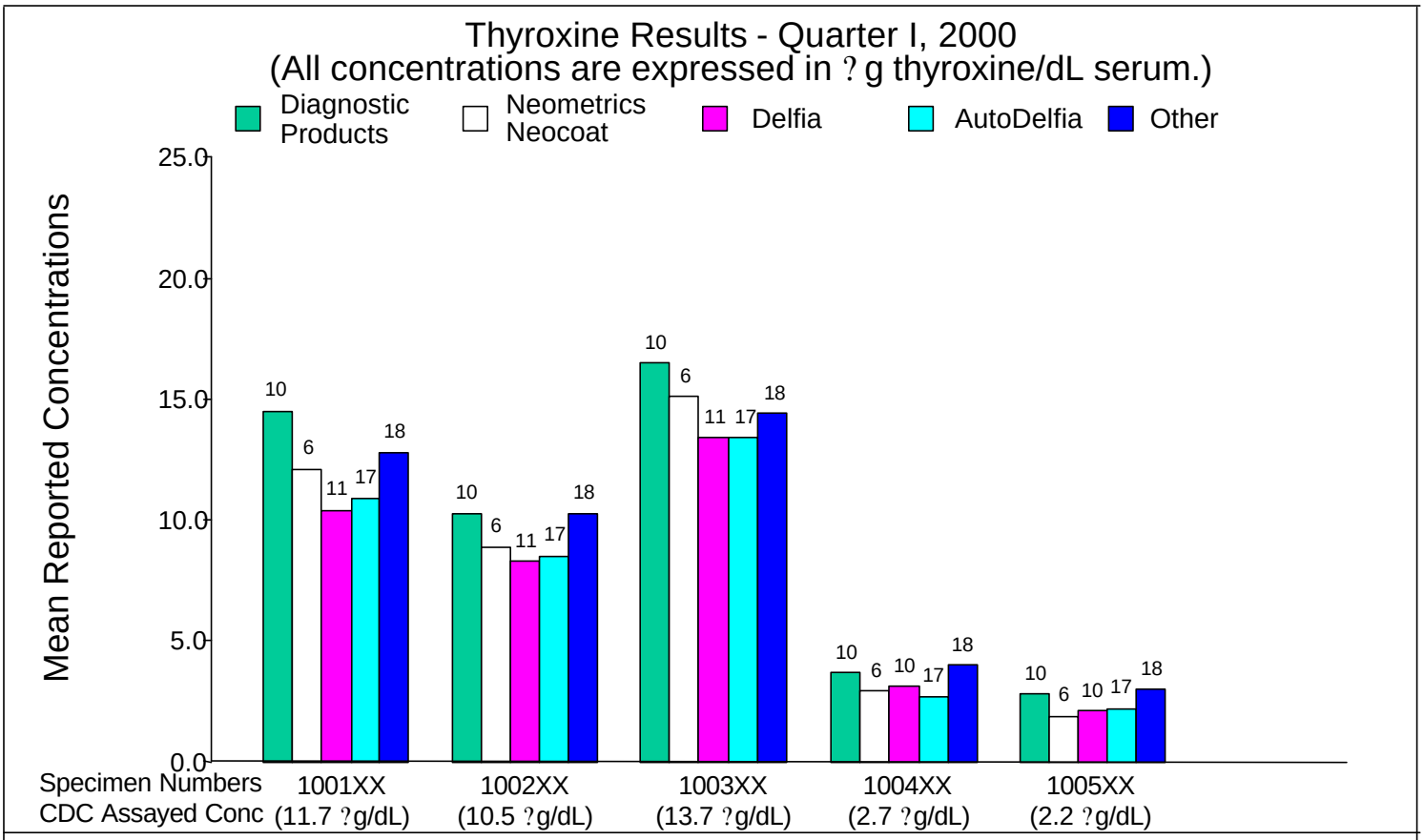
Rudolph P. Hormuth, who was retired from the Department of Health and Human Services as a specialist in services for mentally retarded children, died in Washington, D.C., on March 27, 2000. He was a native of Kleinforste, Germany. His family settled in Brooklyn, New York, in 1926. Rudy was a graduate of St. Francis College, and he received a M.S. in Social Work from Columbia University. He served in the U.S. Army in Alaska during World War II.

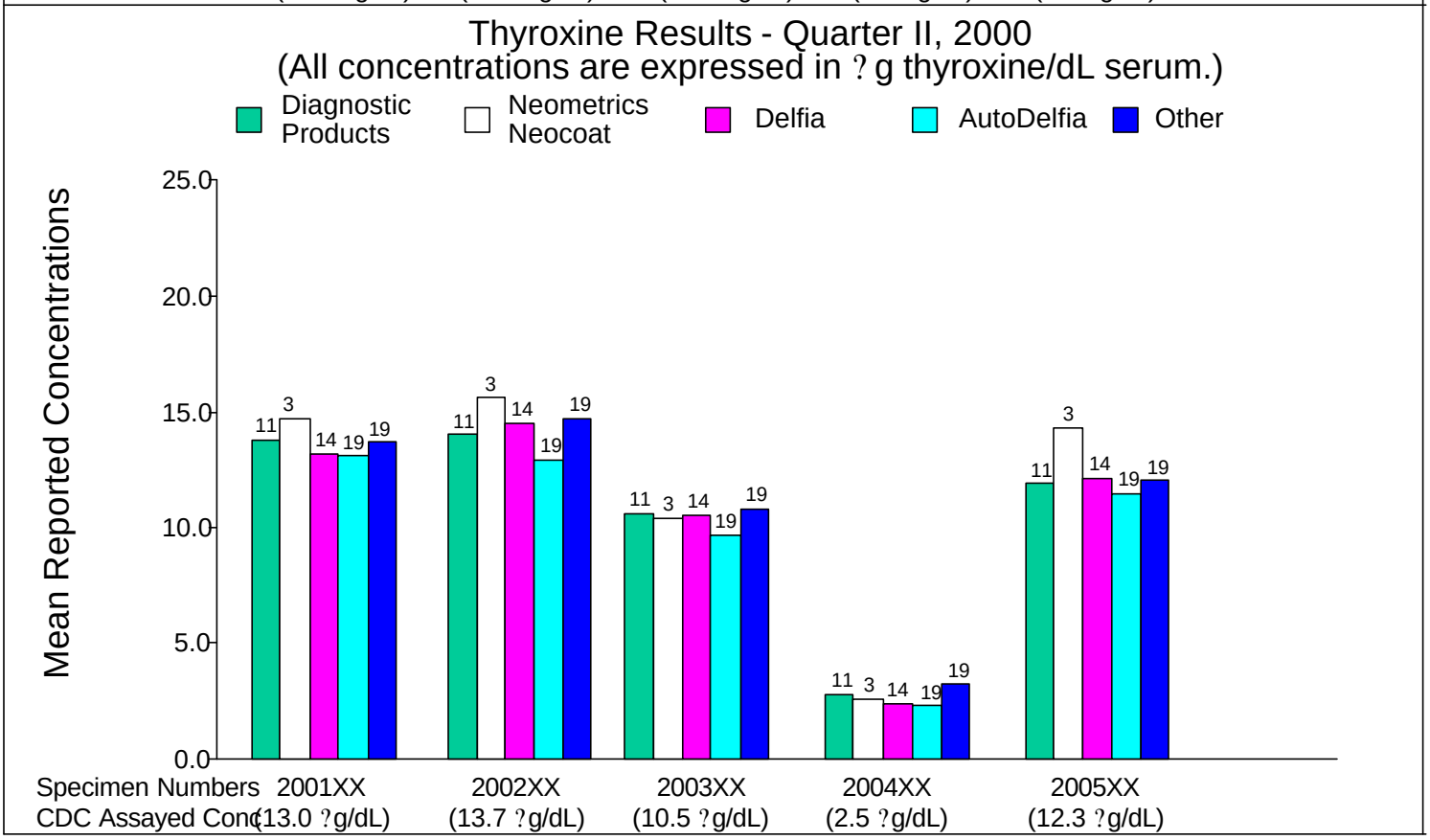
Rudy began his career as a psychiatric social worker at Kings County Hospital in Brooklyn, New York, in 1947. Later, he was a supervisor at the Jewish Hospital of Brooklyn and assistant to the Executive Director of the New York State Association for the Help of Retarded Children.

Rudy joined the Children's Bureau of the Department of Health, Education and Welfare in 1956 as a consultant in mental retardation. His work included the development of screening programs to determine metabolic and genetic disorders in newborns. He was instrumental in the start-up of newborn screening in the United States. It was his dedicated effort, at the federal level, that led to the initial funding of Dr. Robert Guthrie's implementation of population-based testing for PKU. Rudy was able to secure HRSA support and the initial funding for development of the Newborn Screening Quality Assurance Program. He was our project officer for many years and was highly supportive of our program. He also secured funding for the Newborn Screening Review Team that has been assisting state health departments since 1987. In 1994, he retired from the Genetic Services Bureau of the U.S. Public Health Service.

Rudy was a true friend of the newborn screening community and is greatly missed by all of us. For his countless contributions, we dedicate this Newborn Screening Quality Assurance Program Annual Summary Report to his memory.

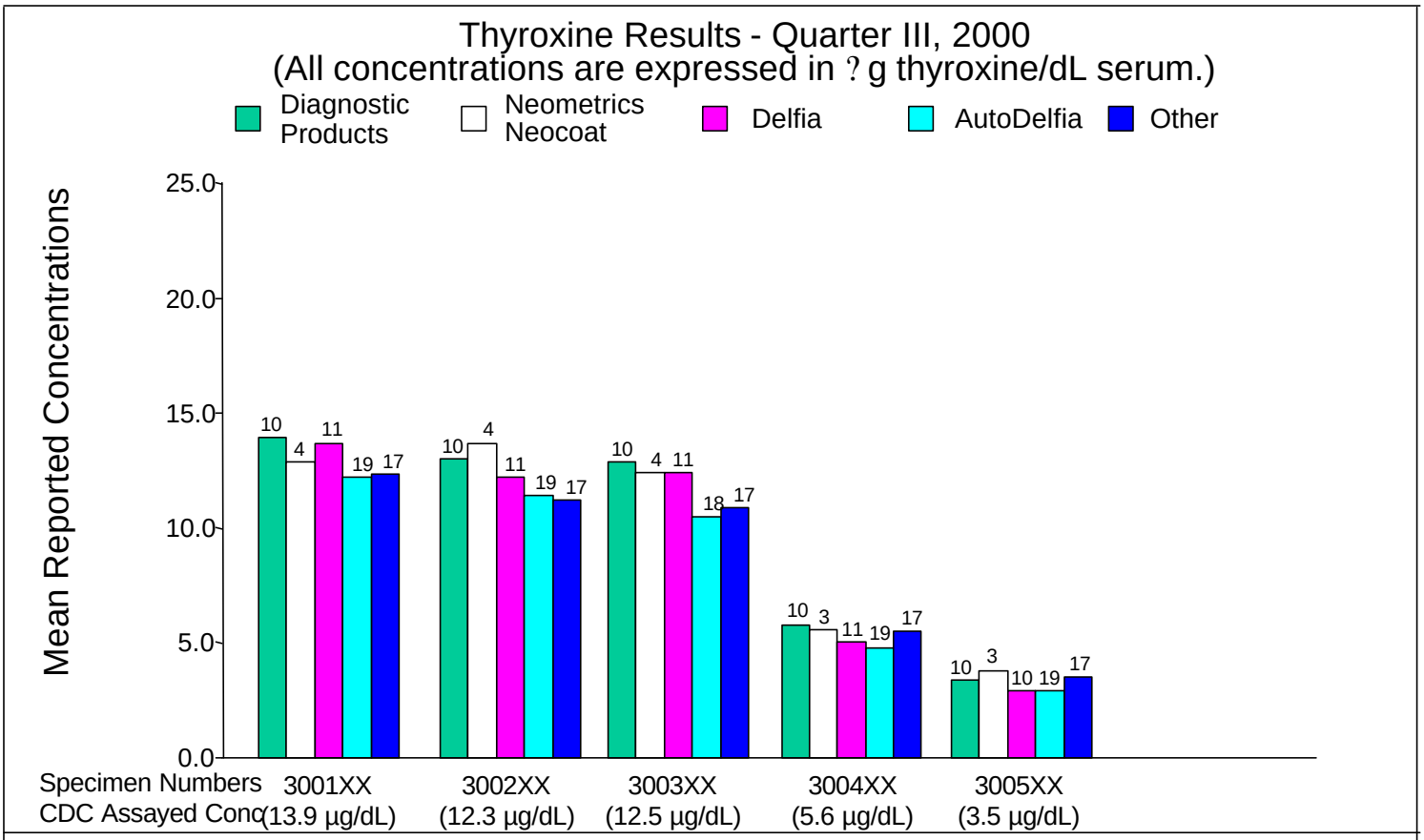
2000 Performance Evaluation Data
Mean Reported Concentration By Specimen Numbers

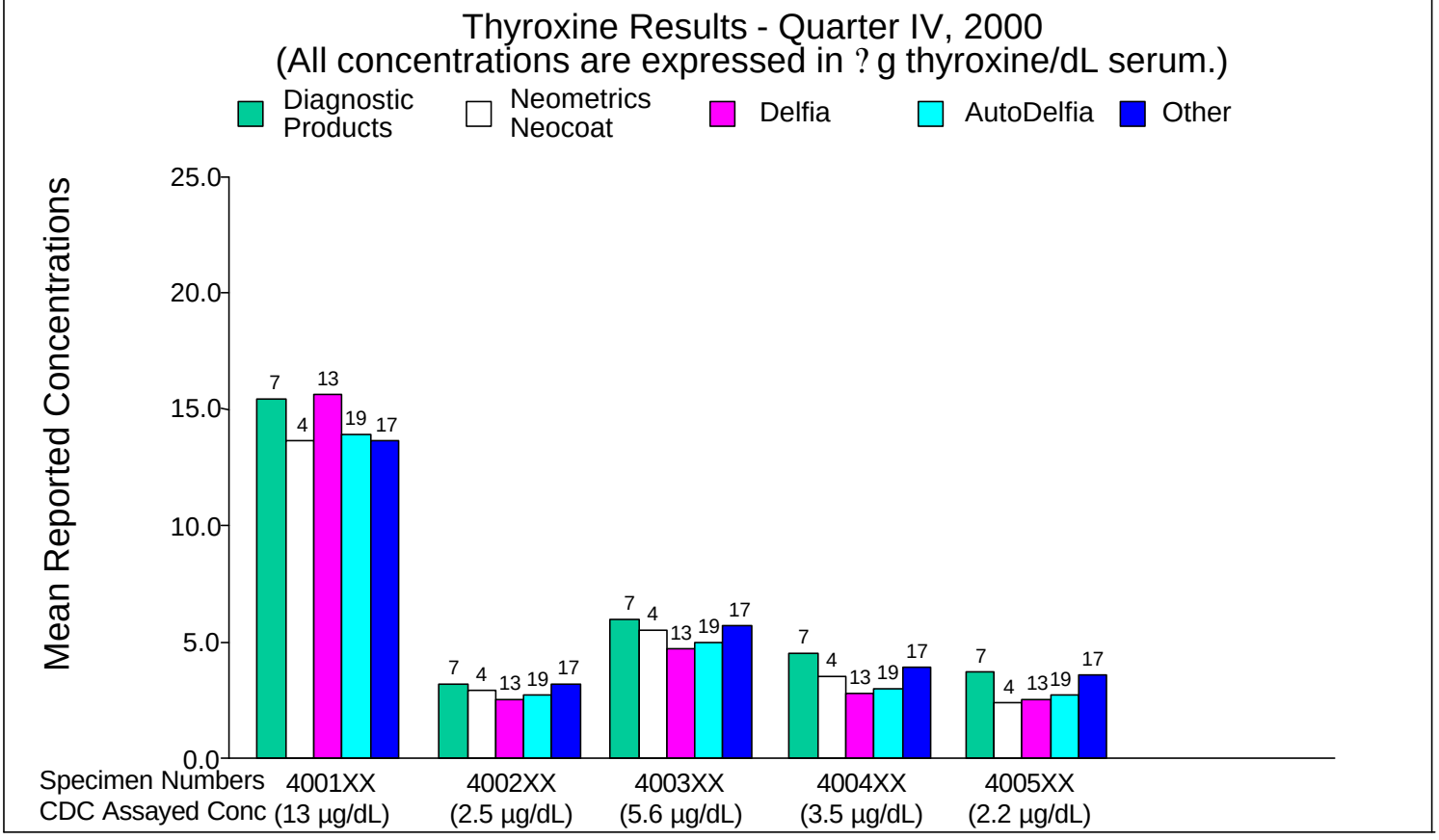




The numbers of observations from which the mean reported concentrations were determined are shown above the bars.

2000 Performance Evaluation Data
Mean Reported Concentration By Specimen Numbers





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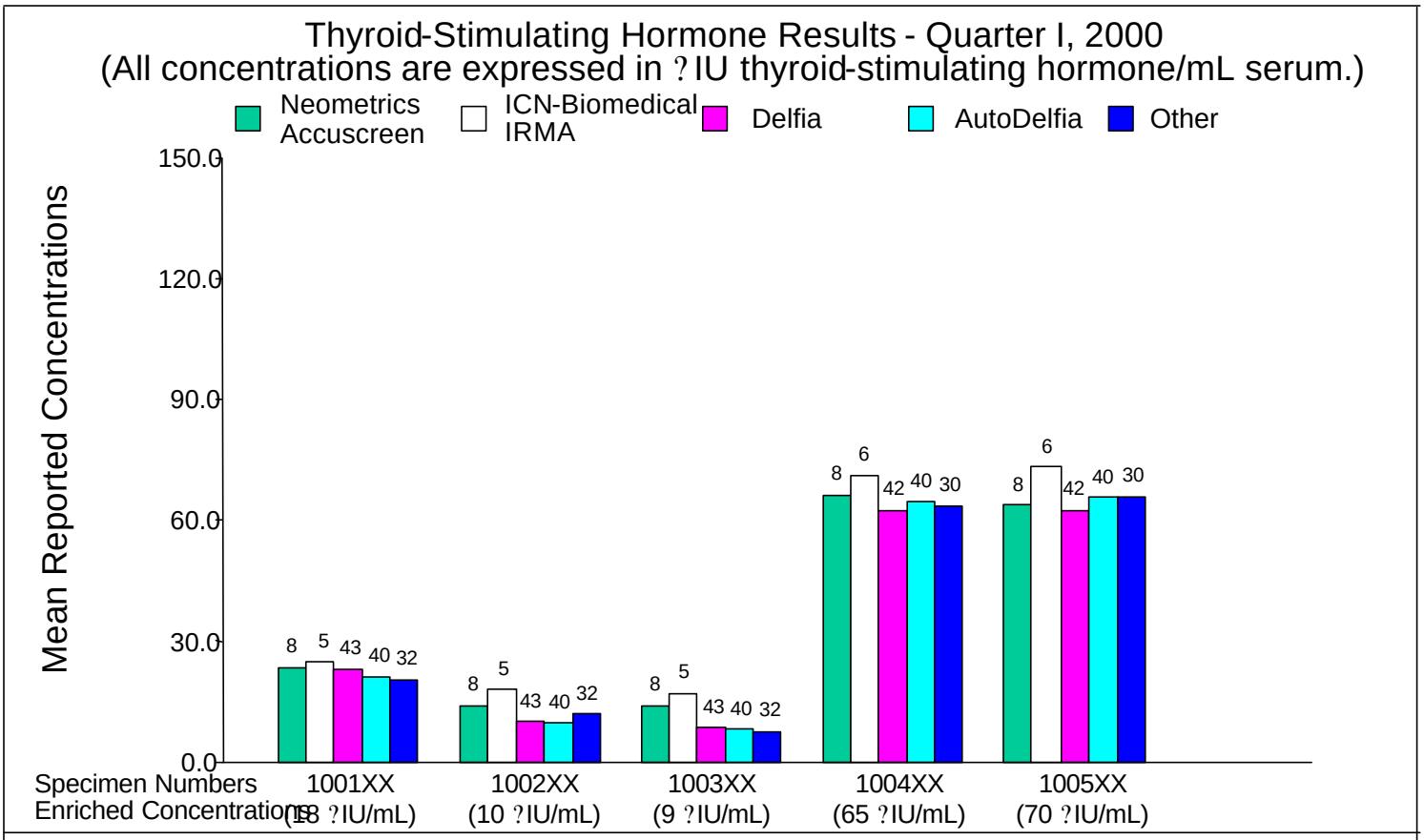

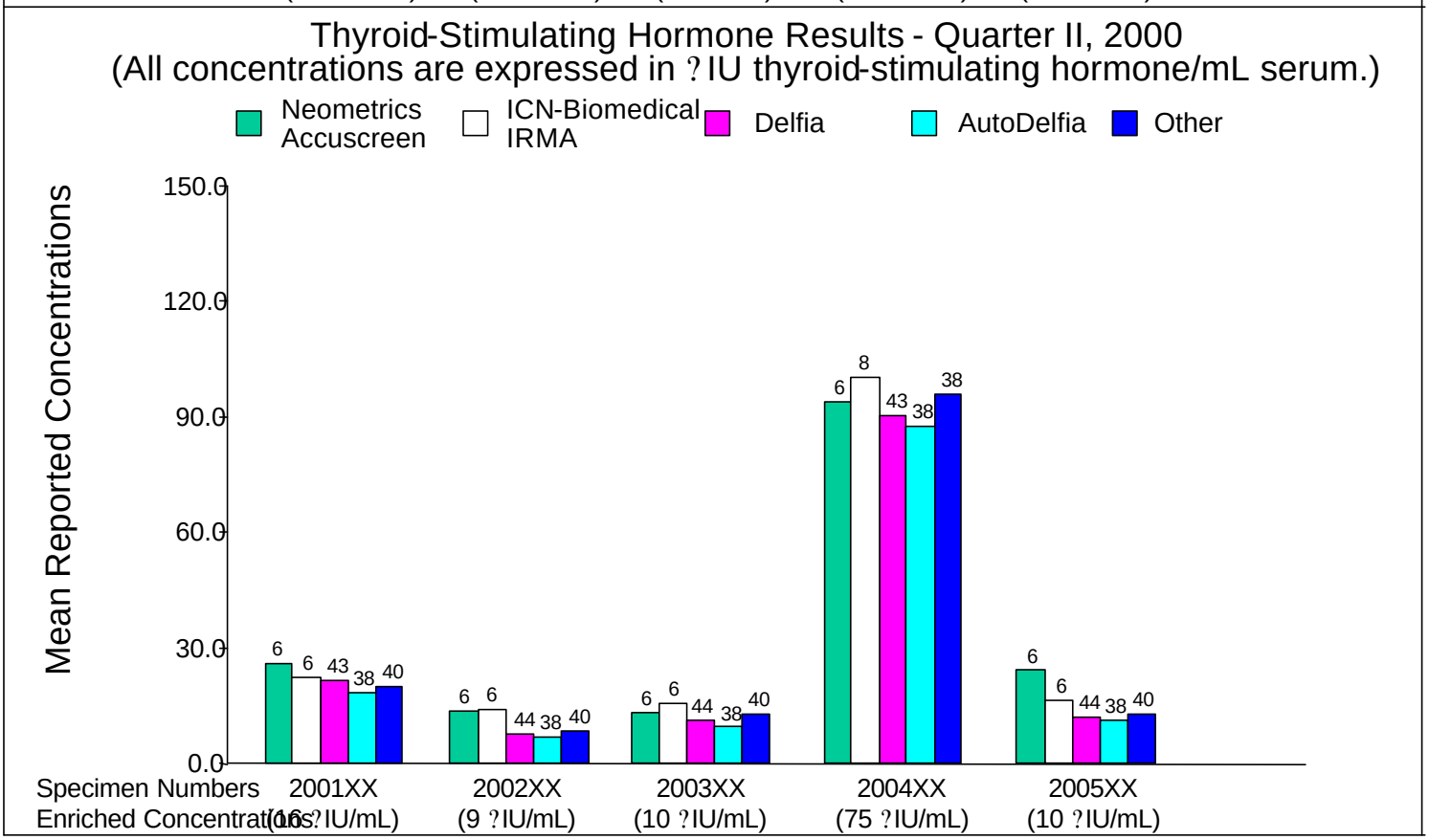

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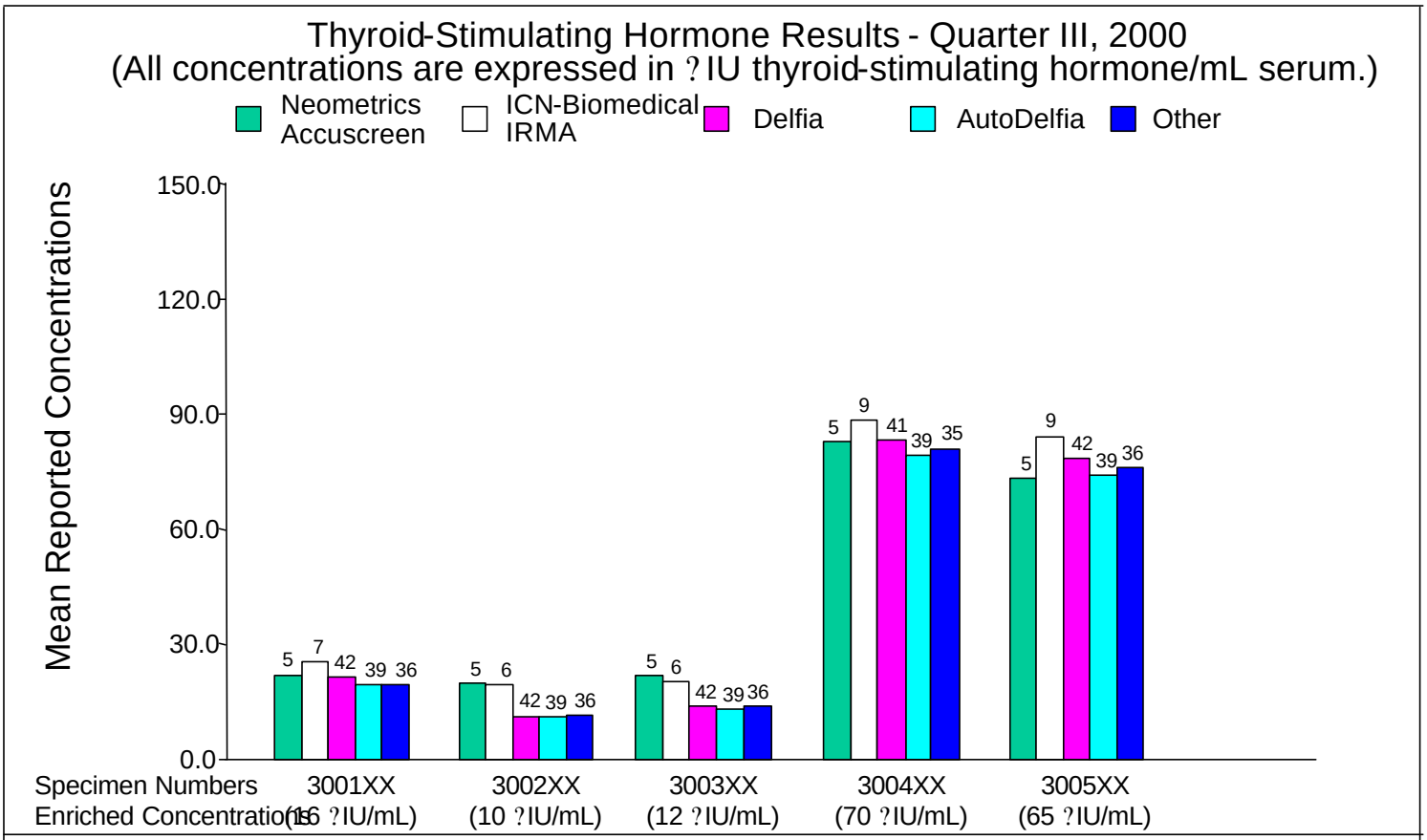

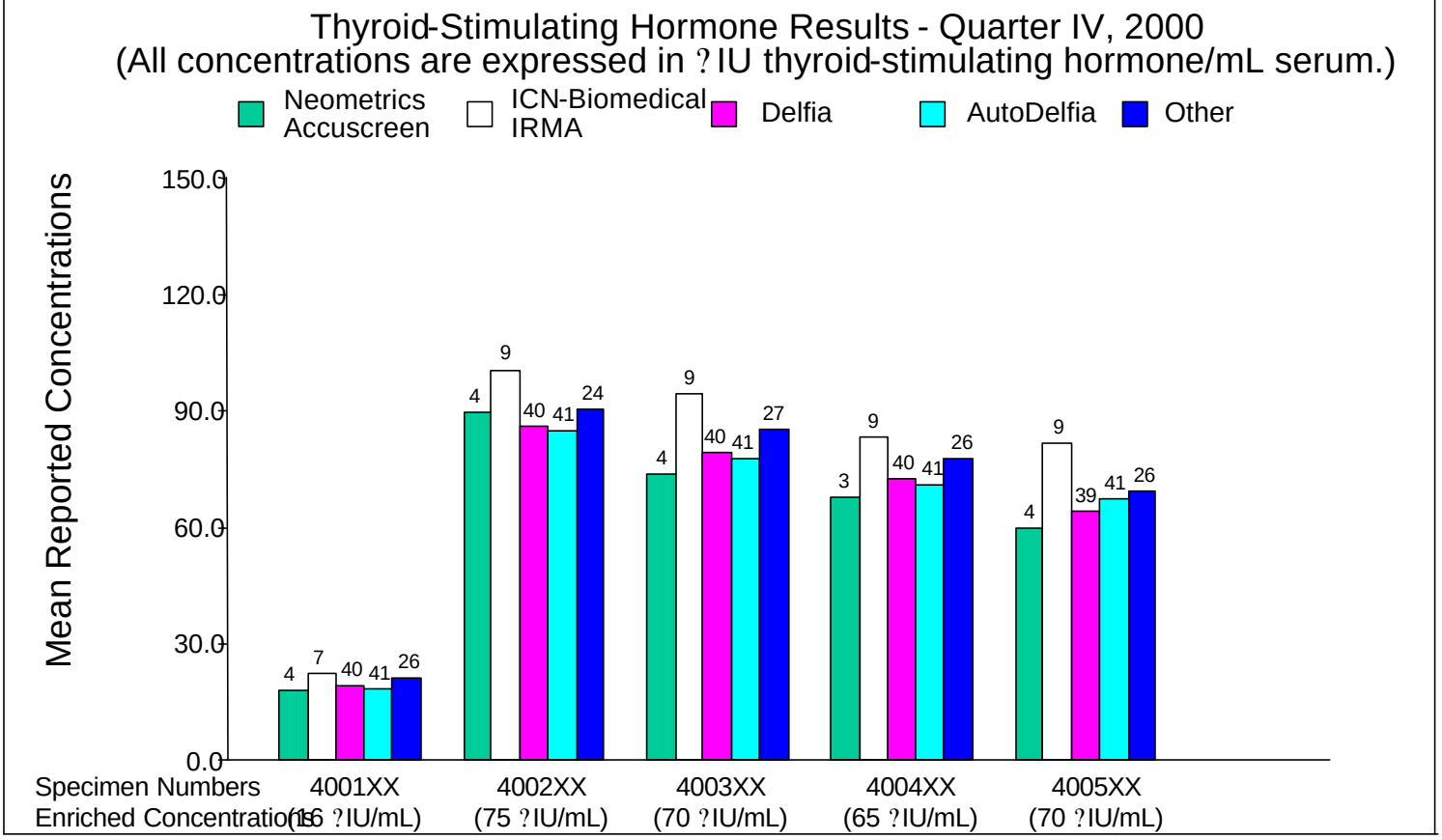

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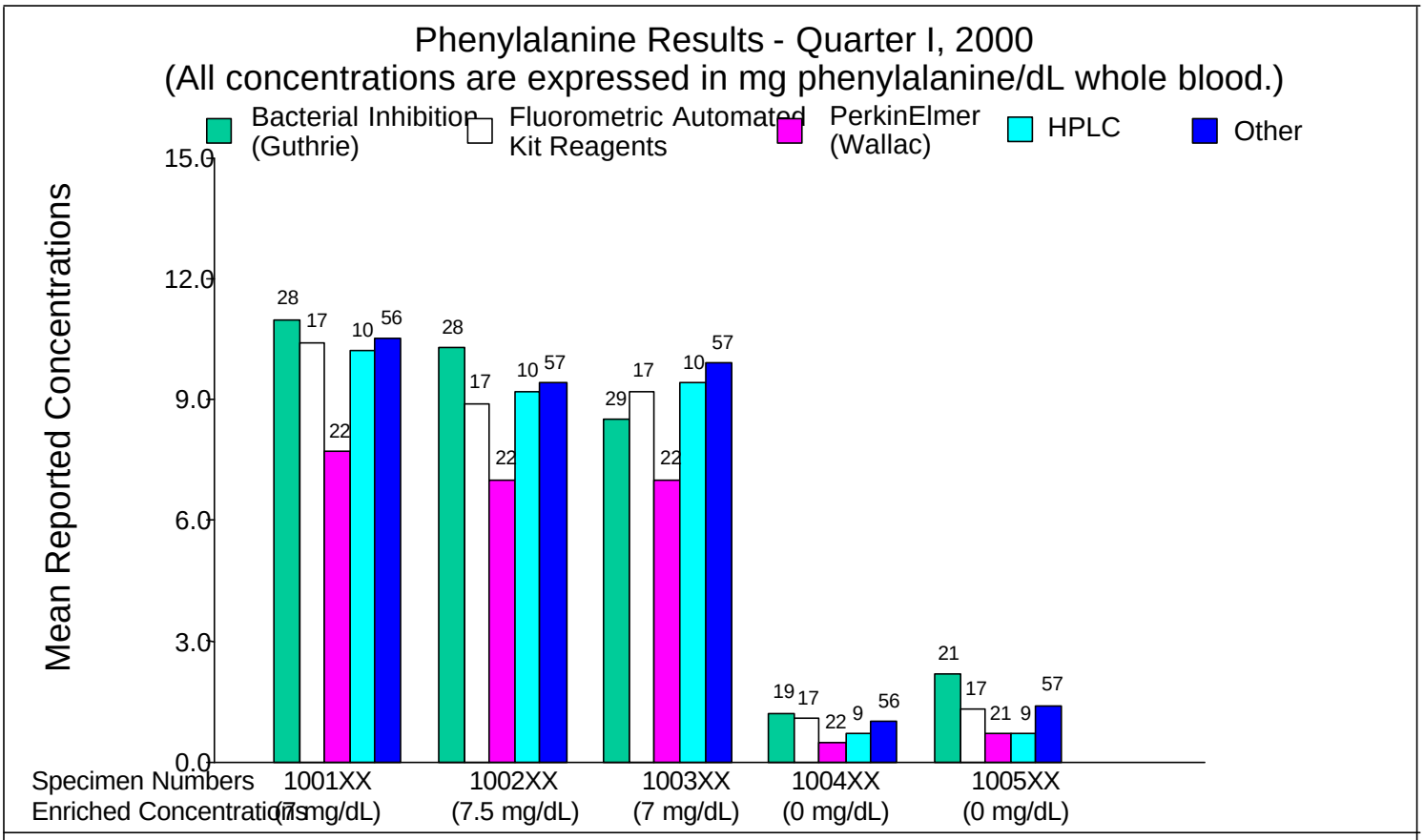

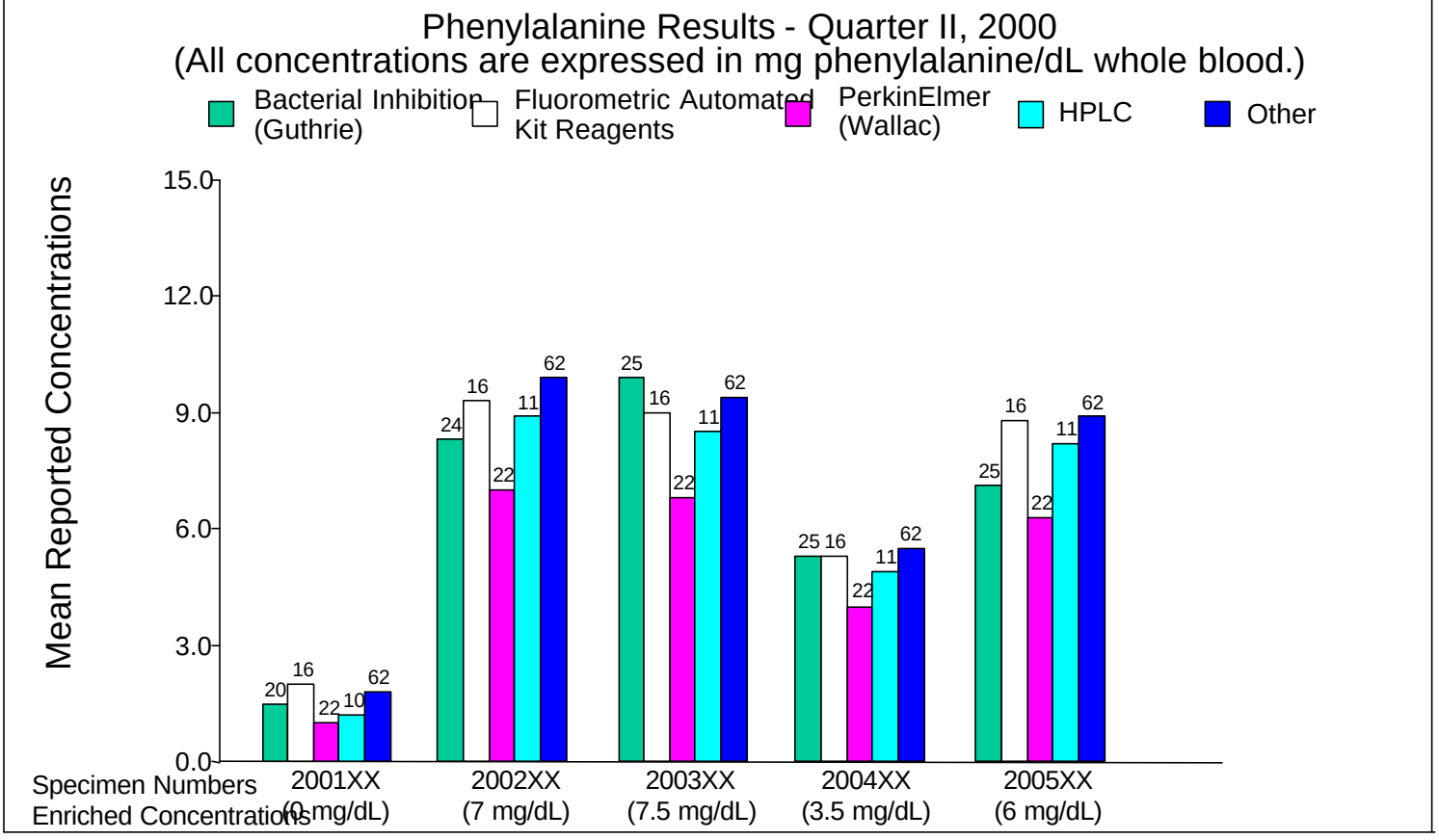

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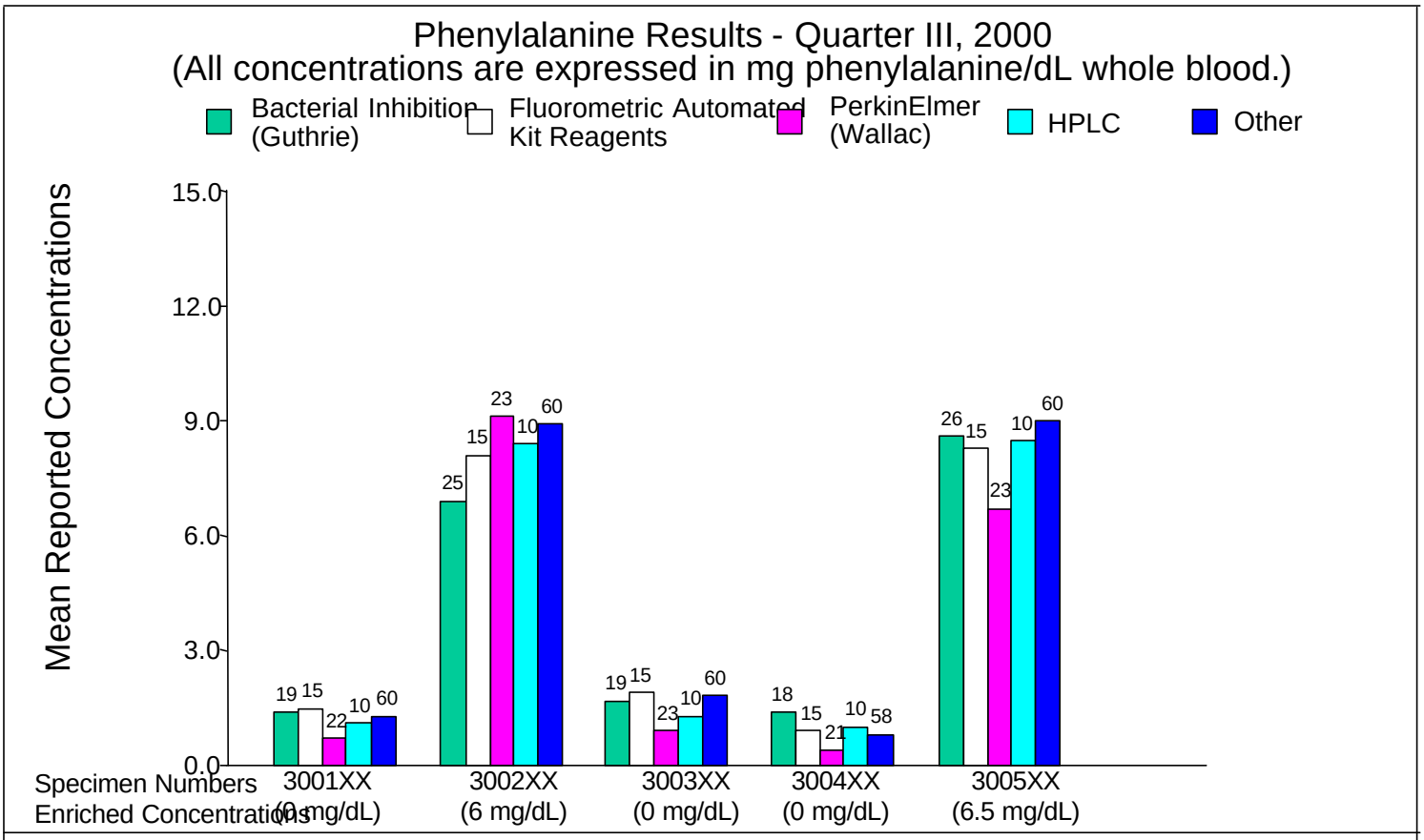

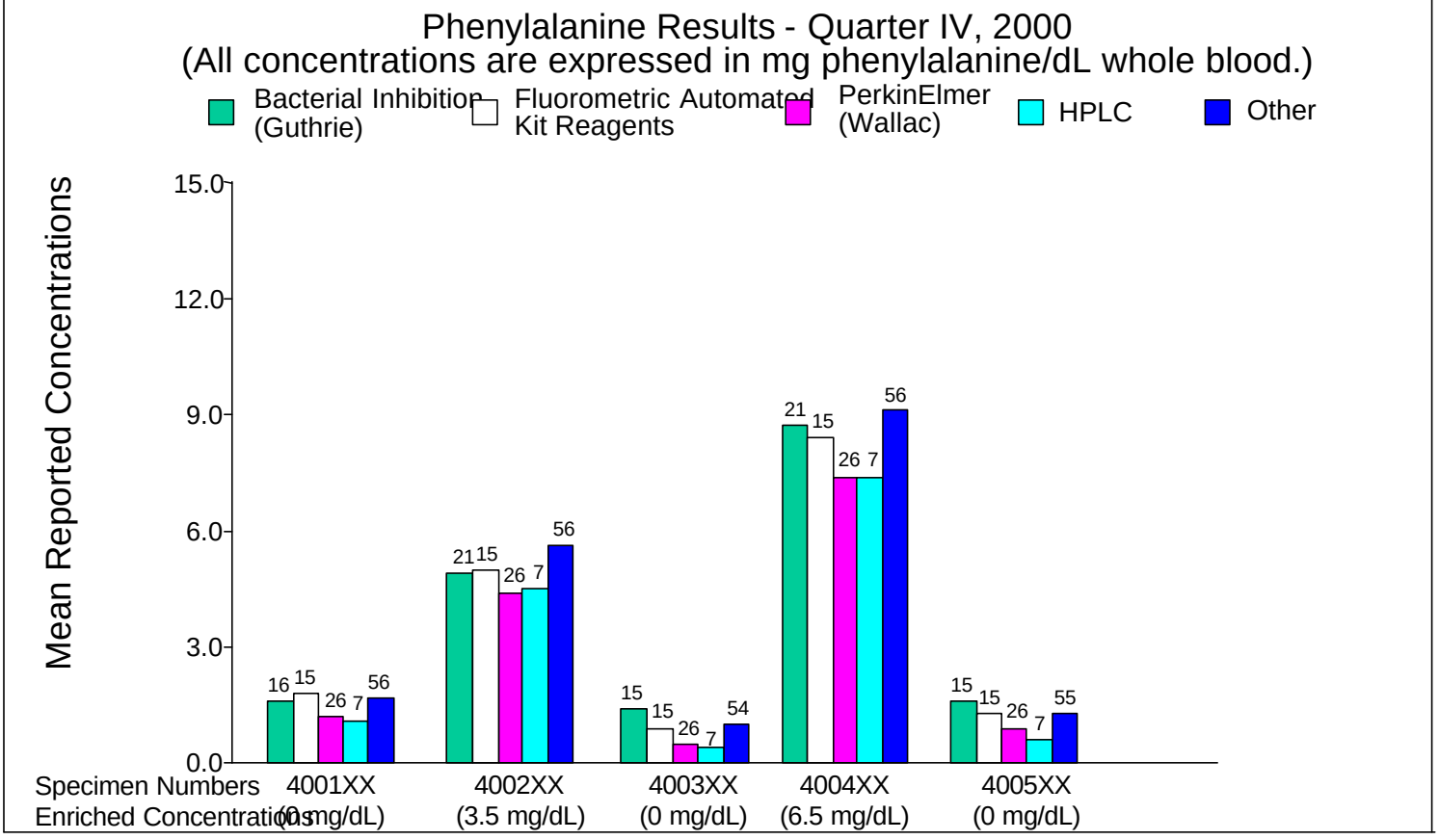

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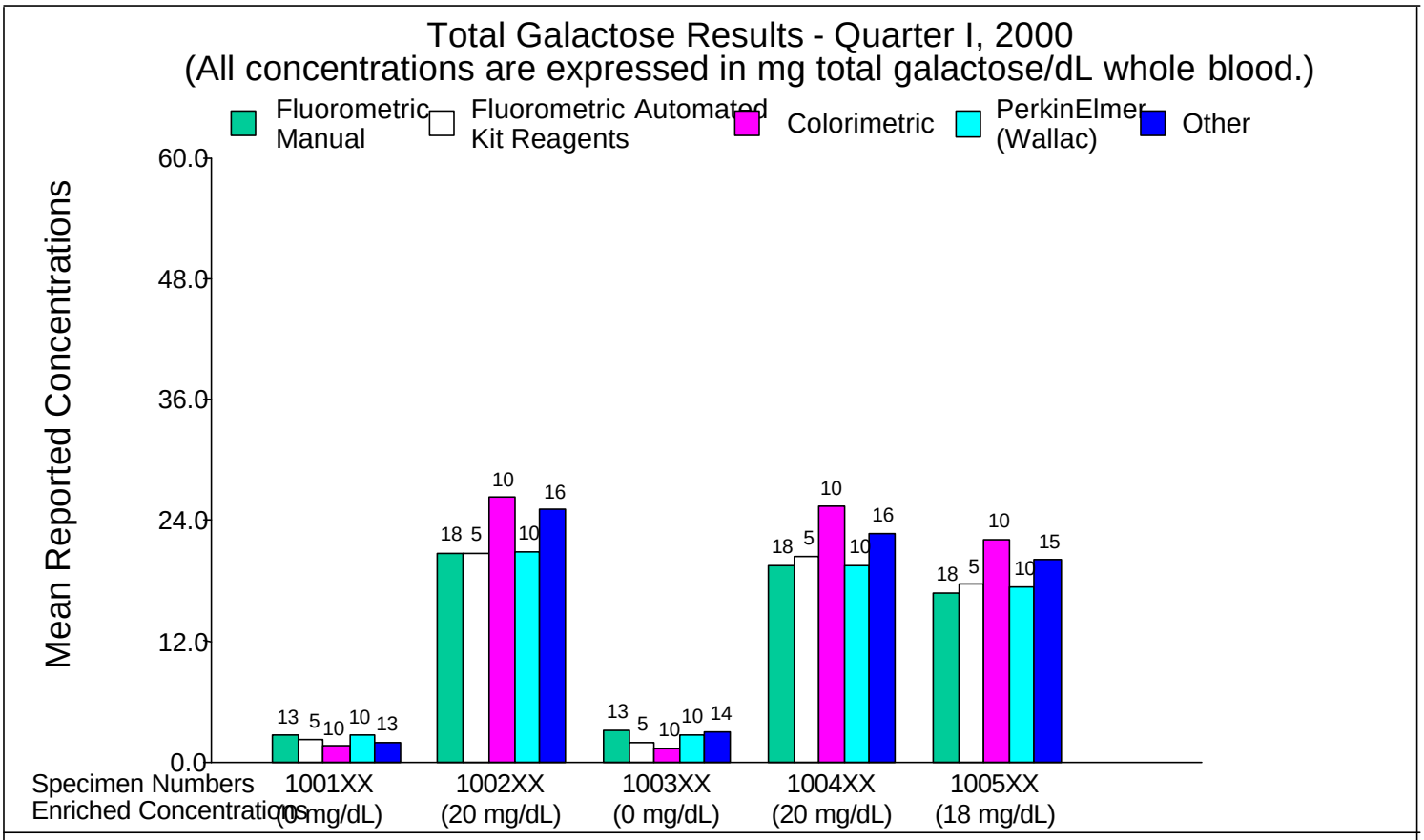

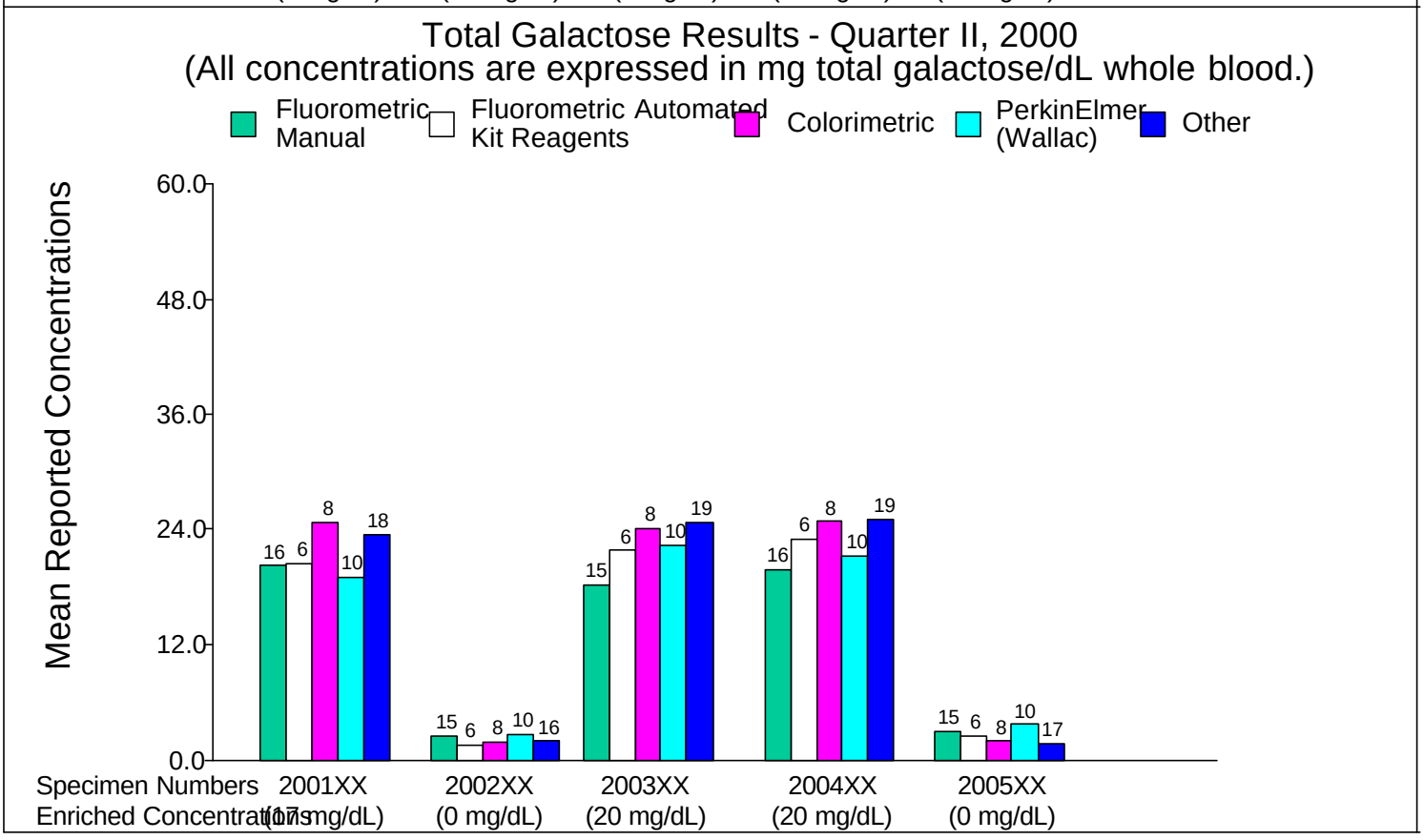

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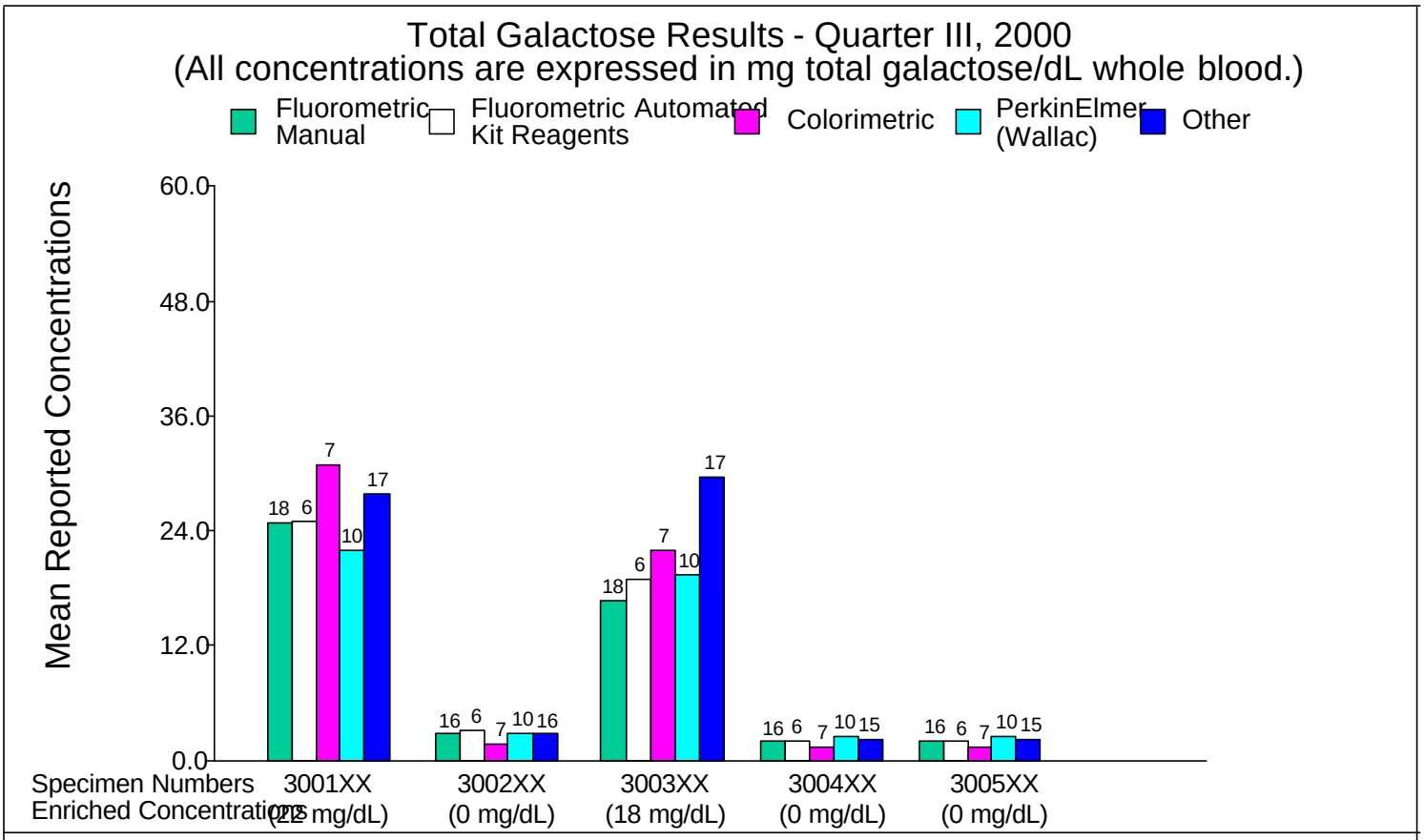

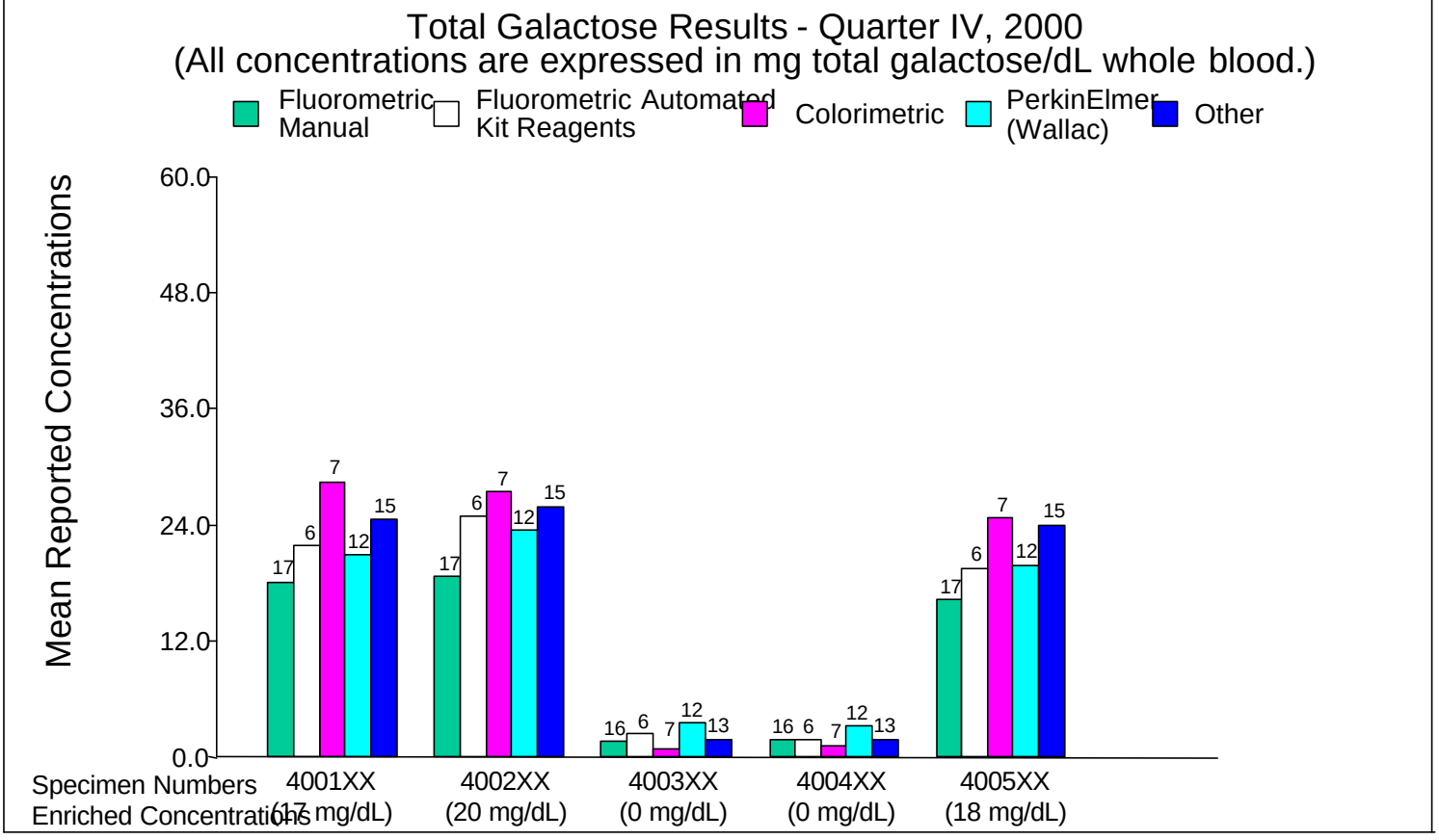

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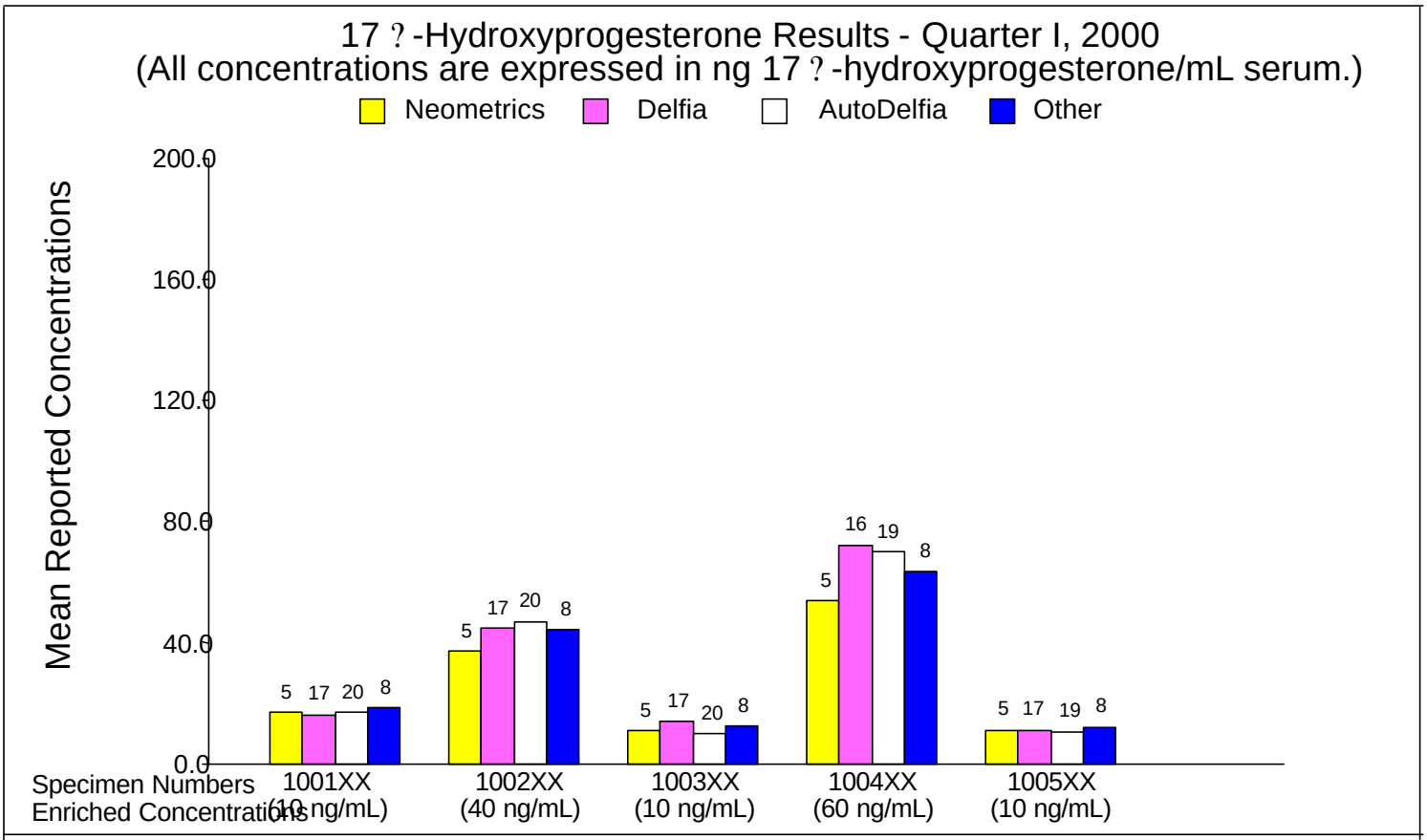

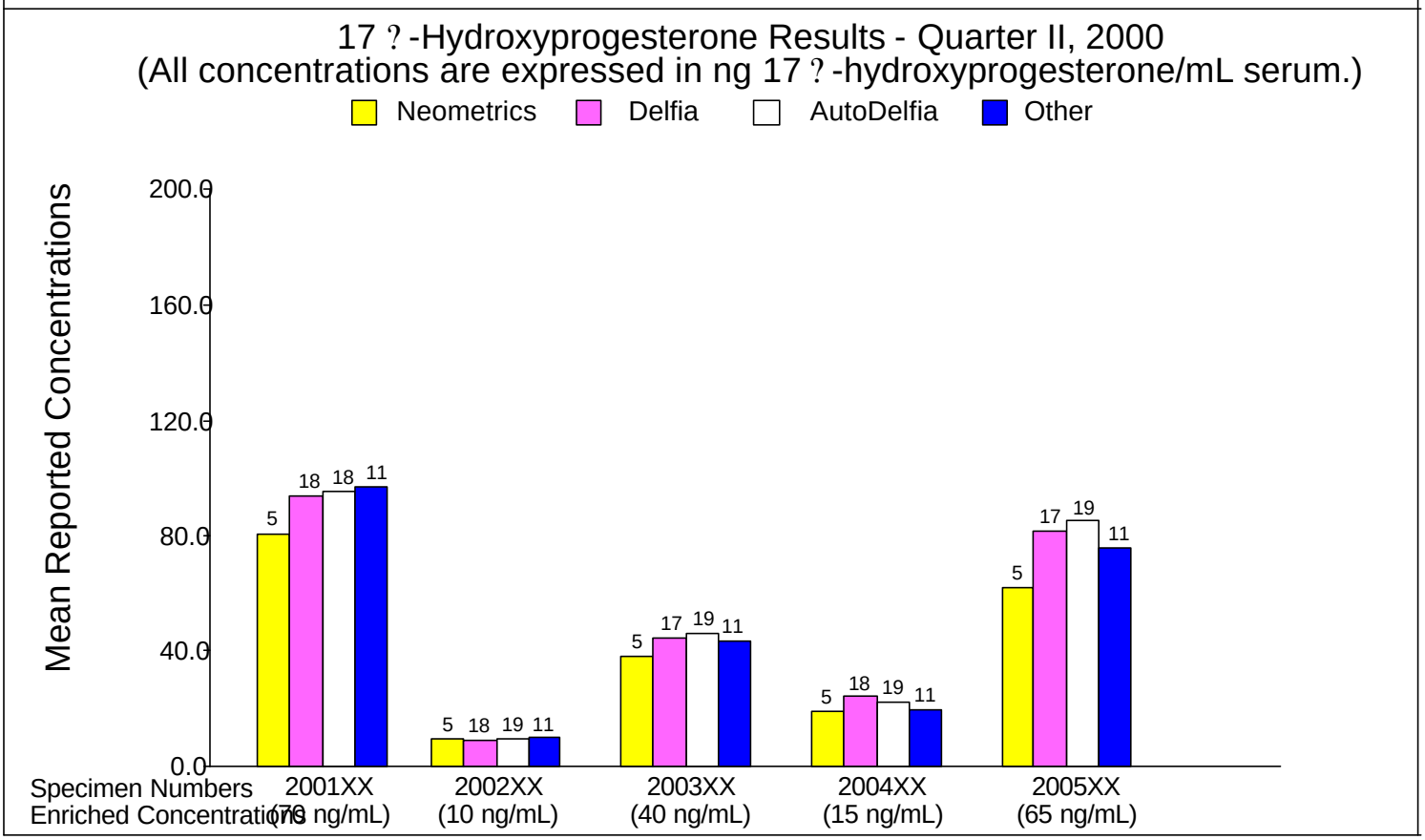

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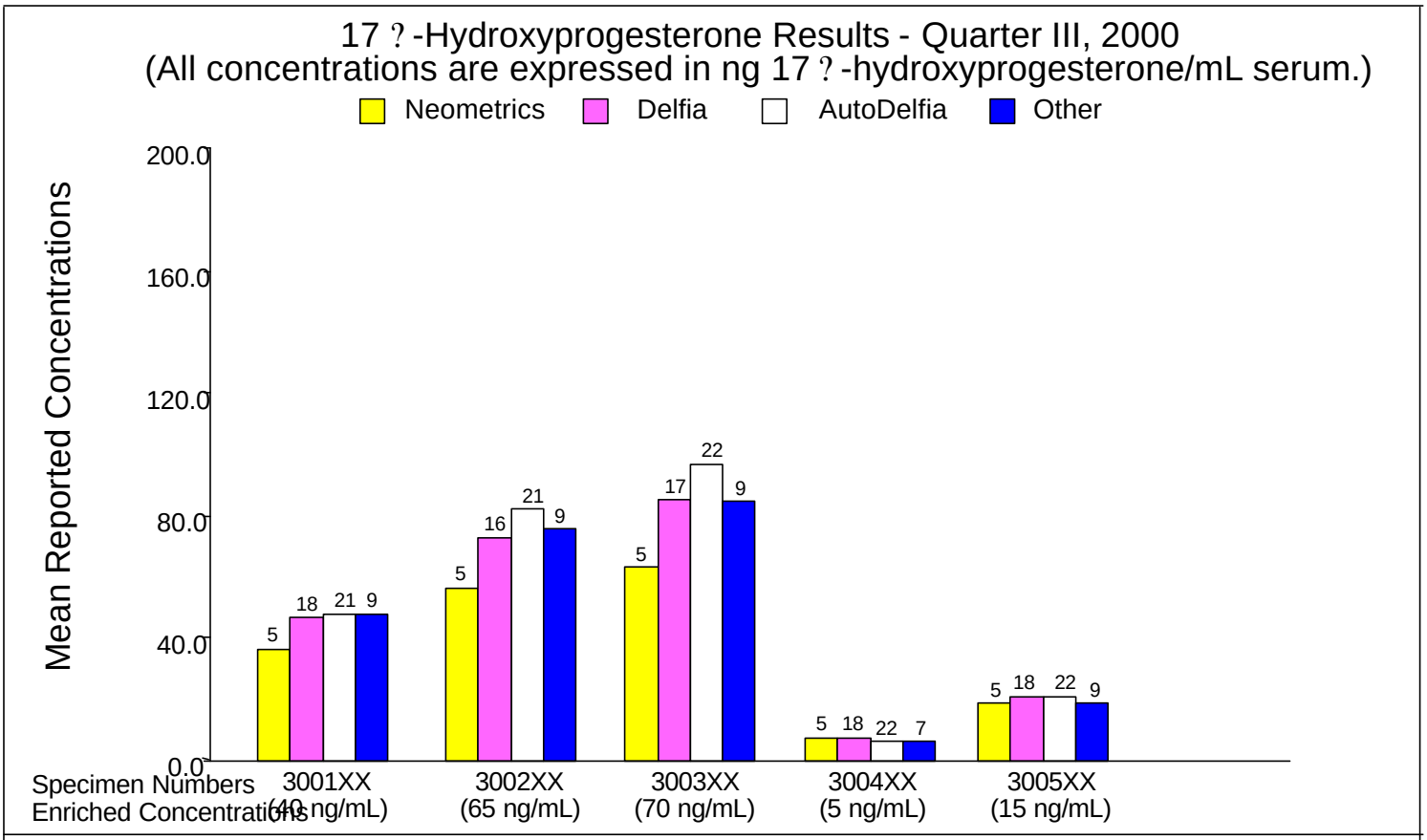

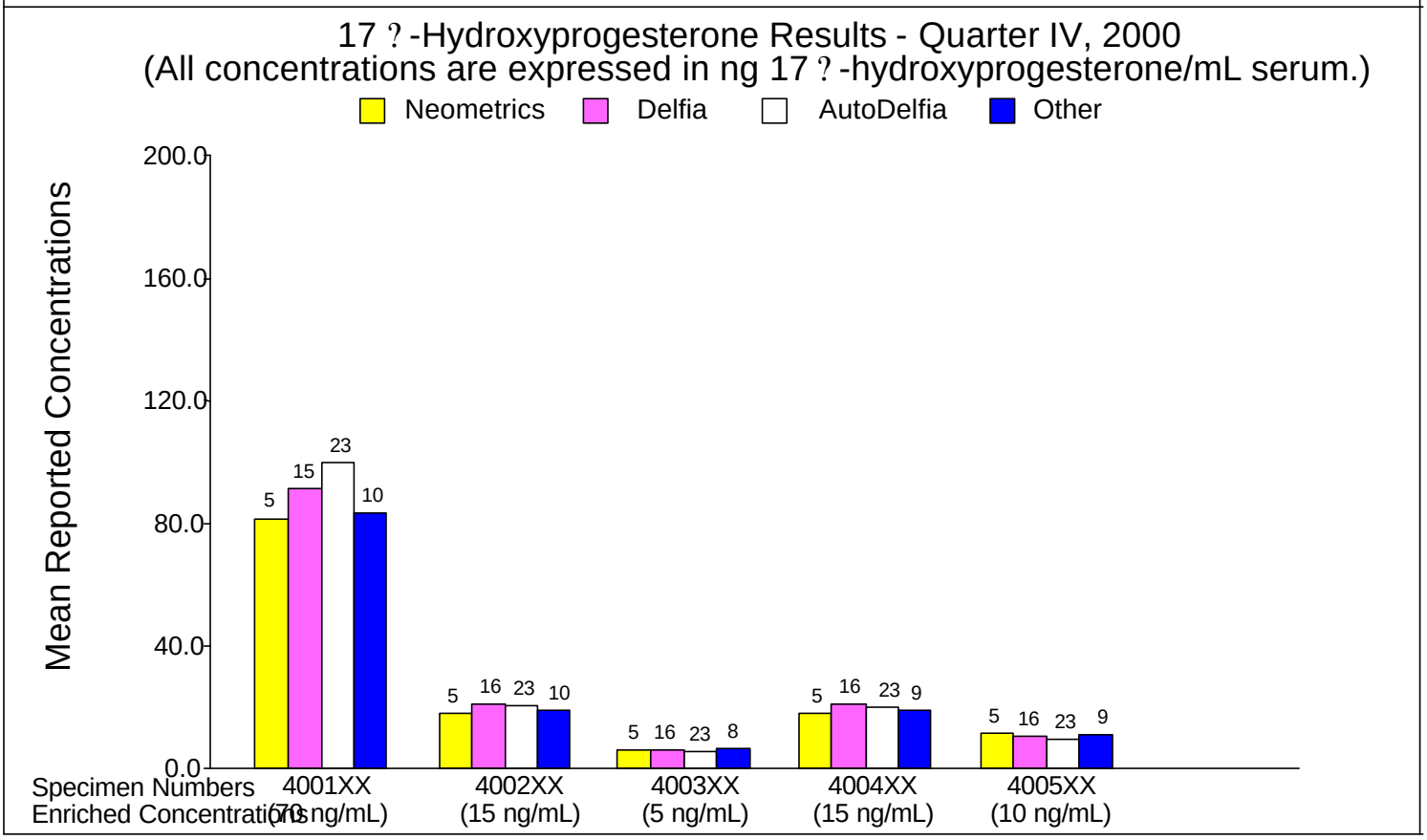

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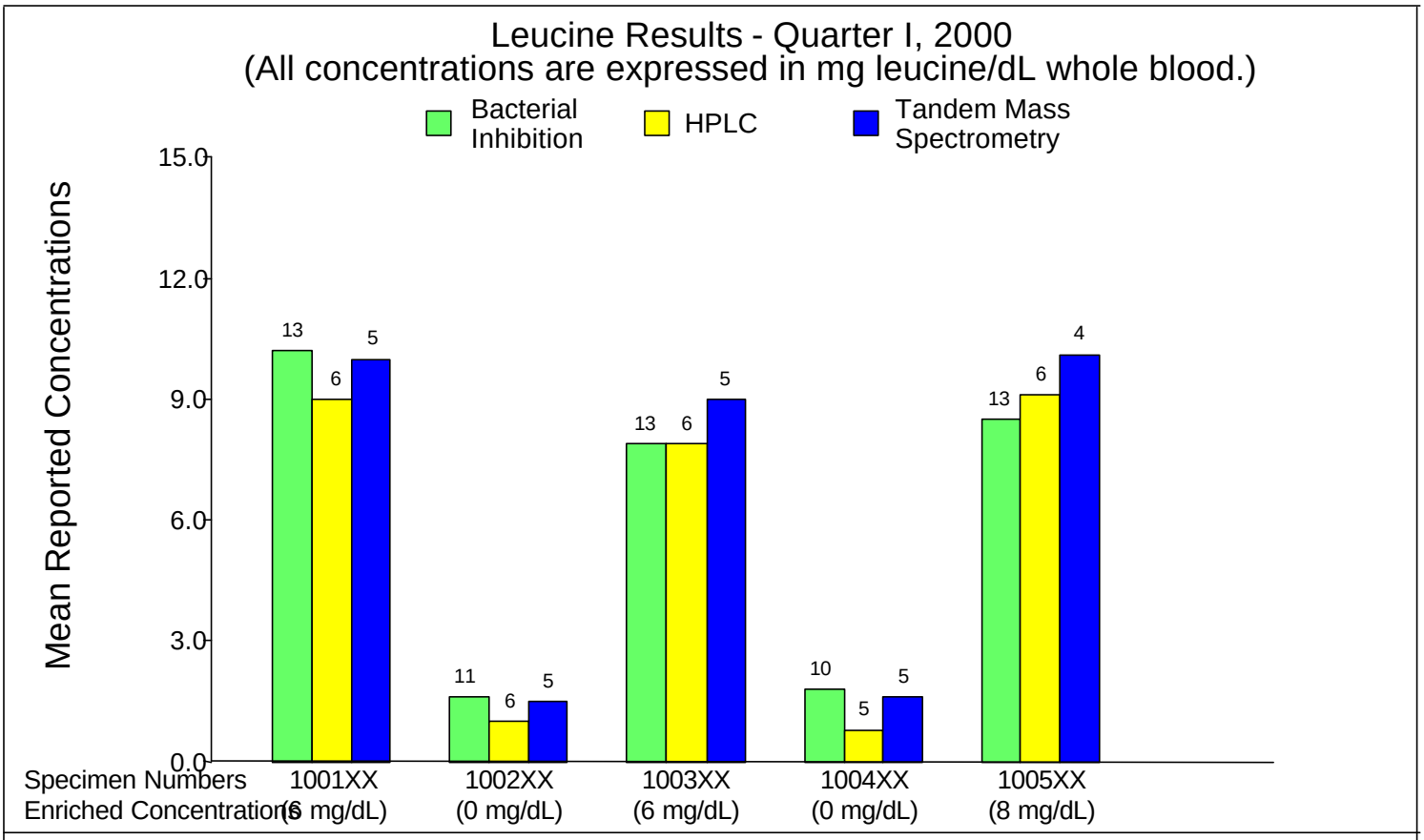

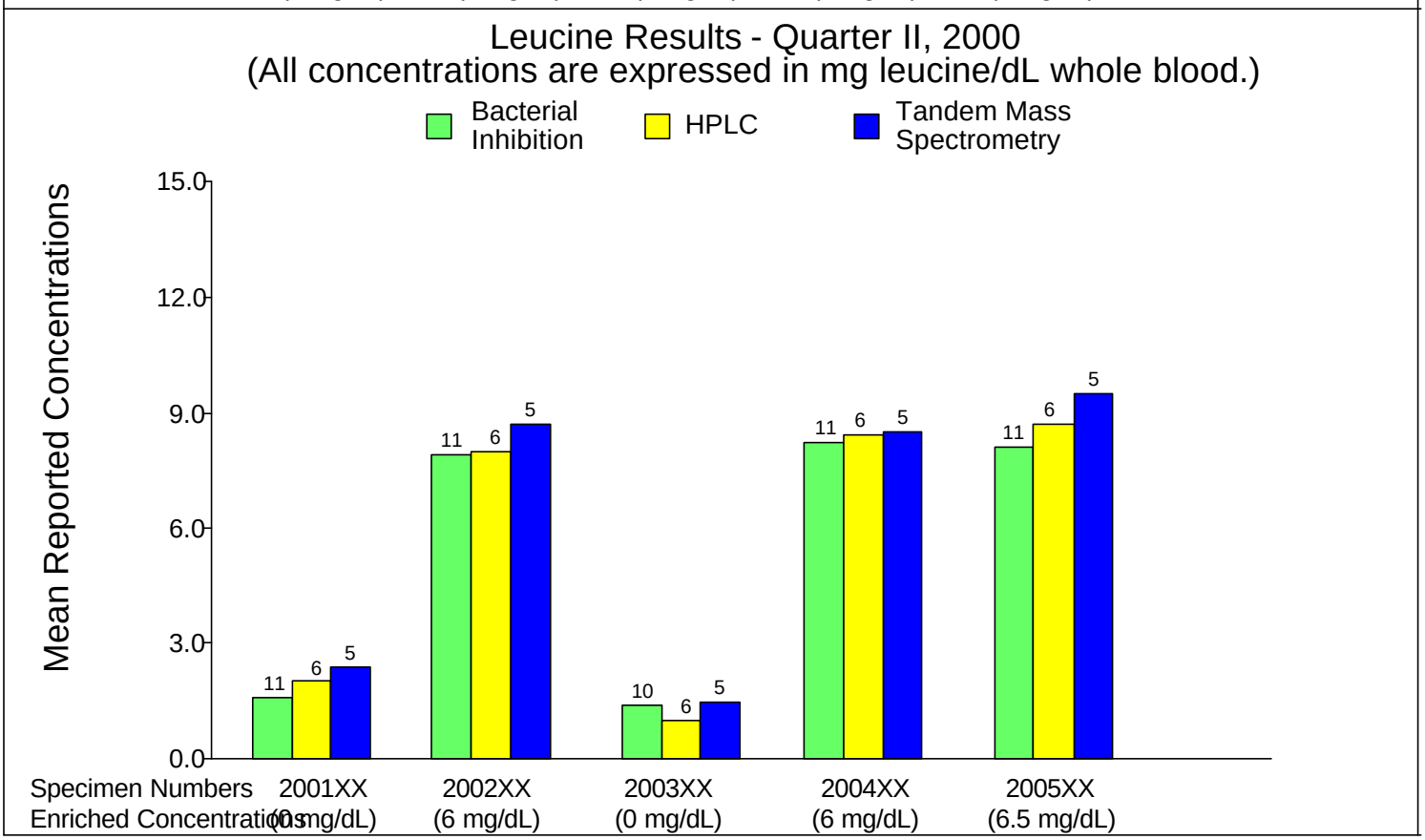

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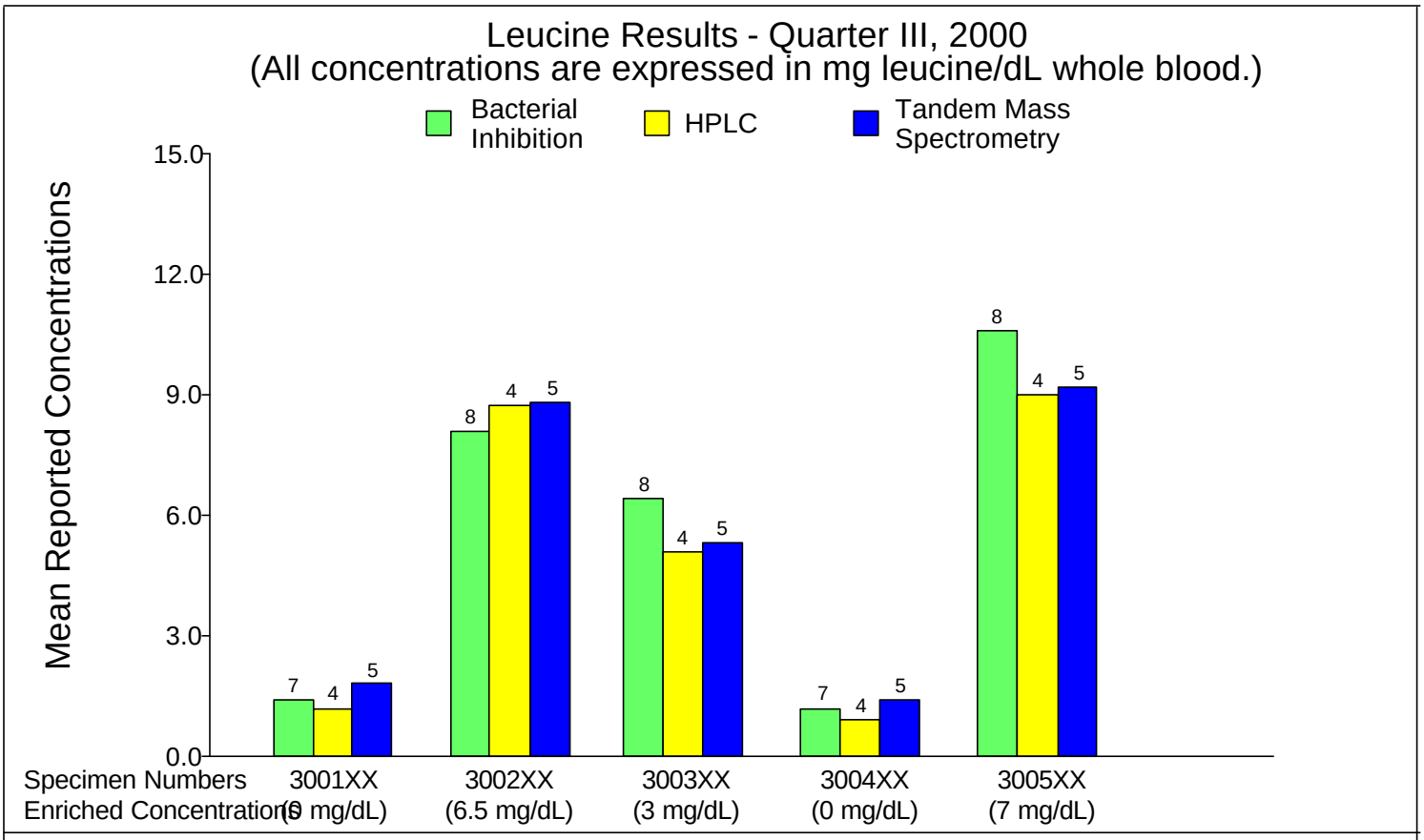

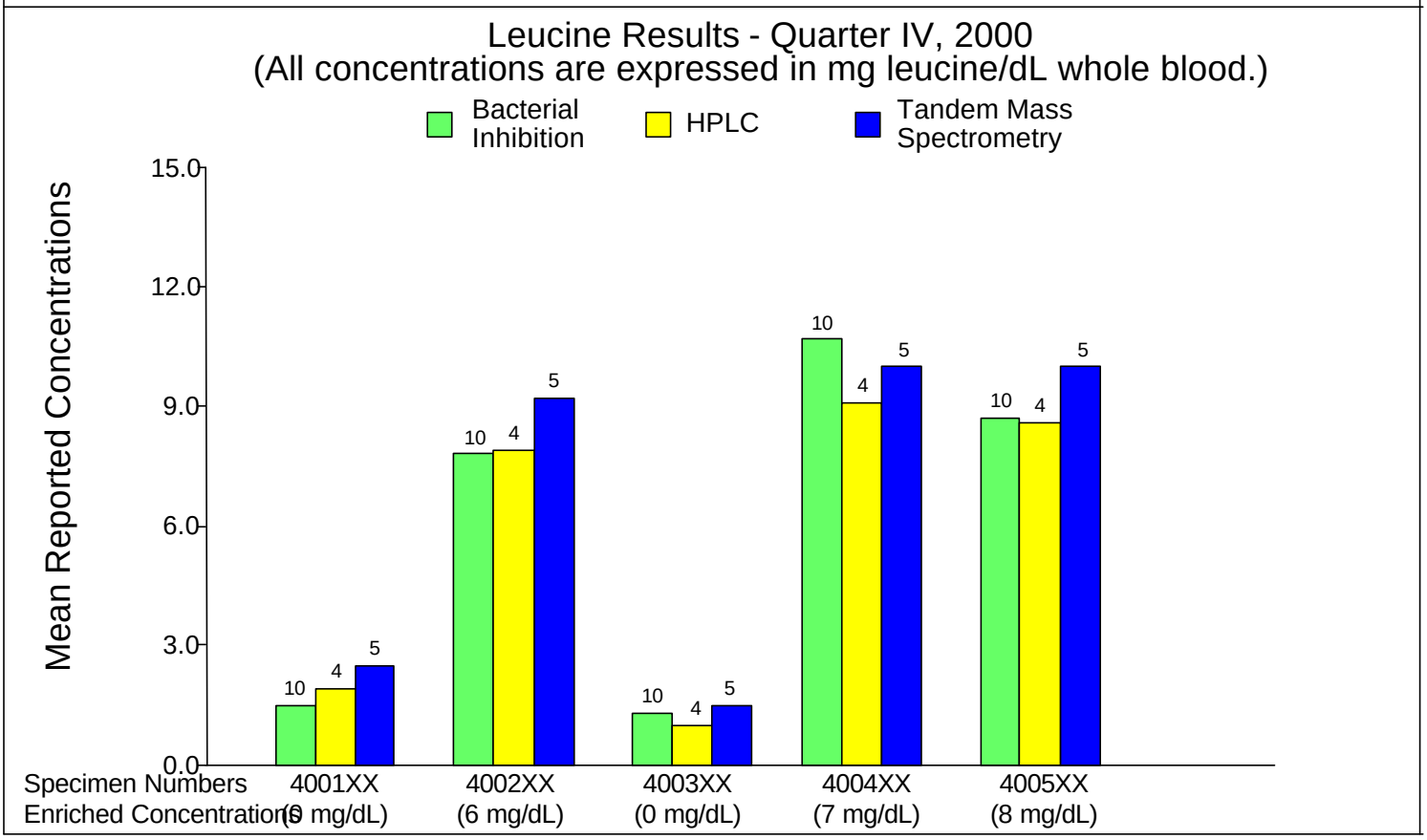

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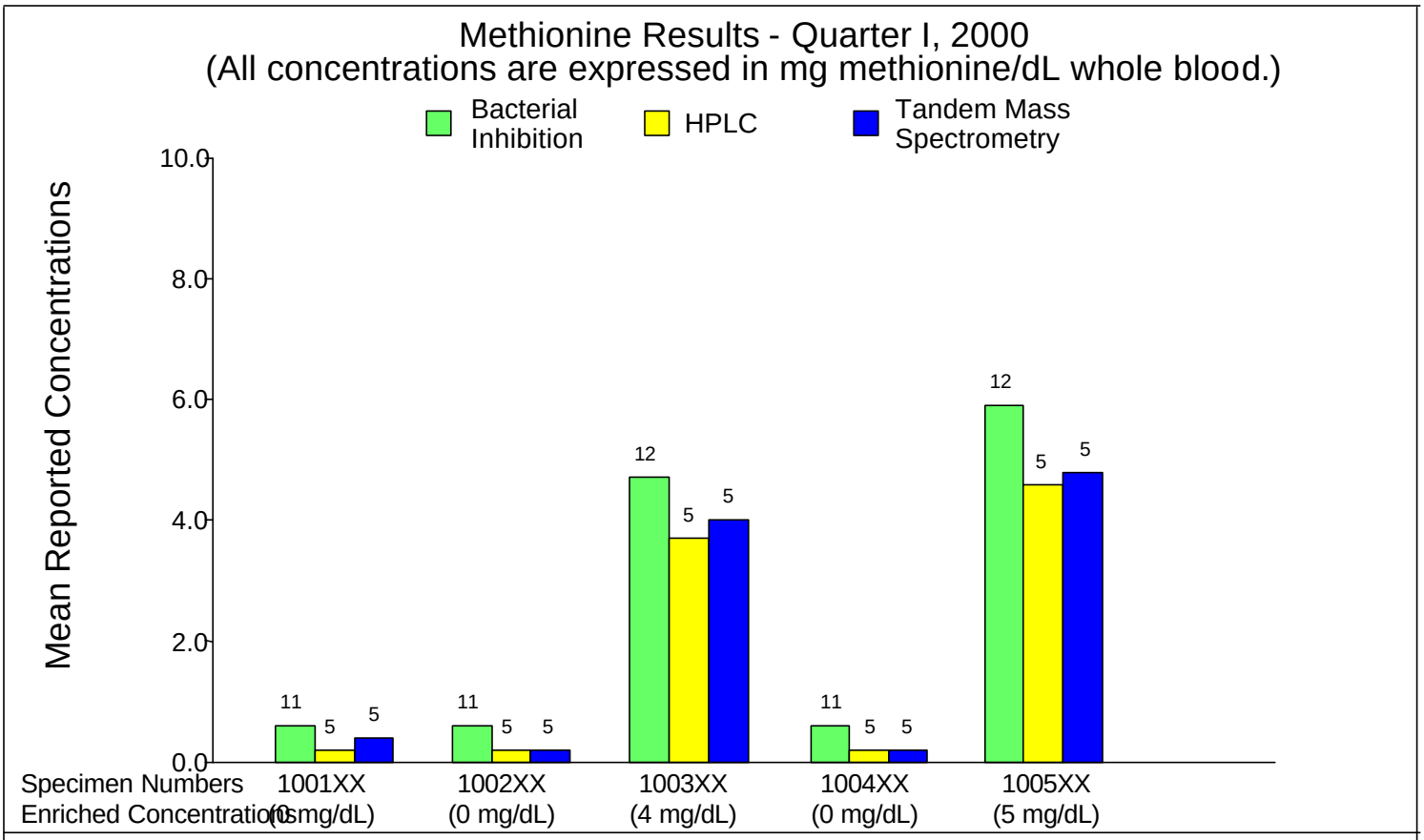

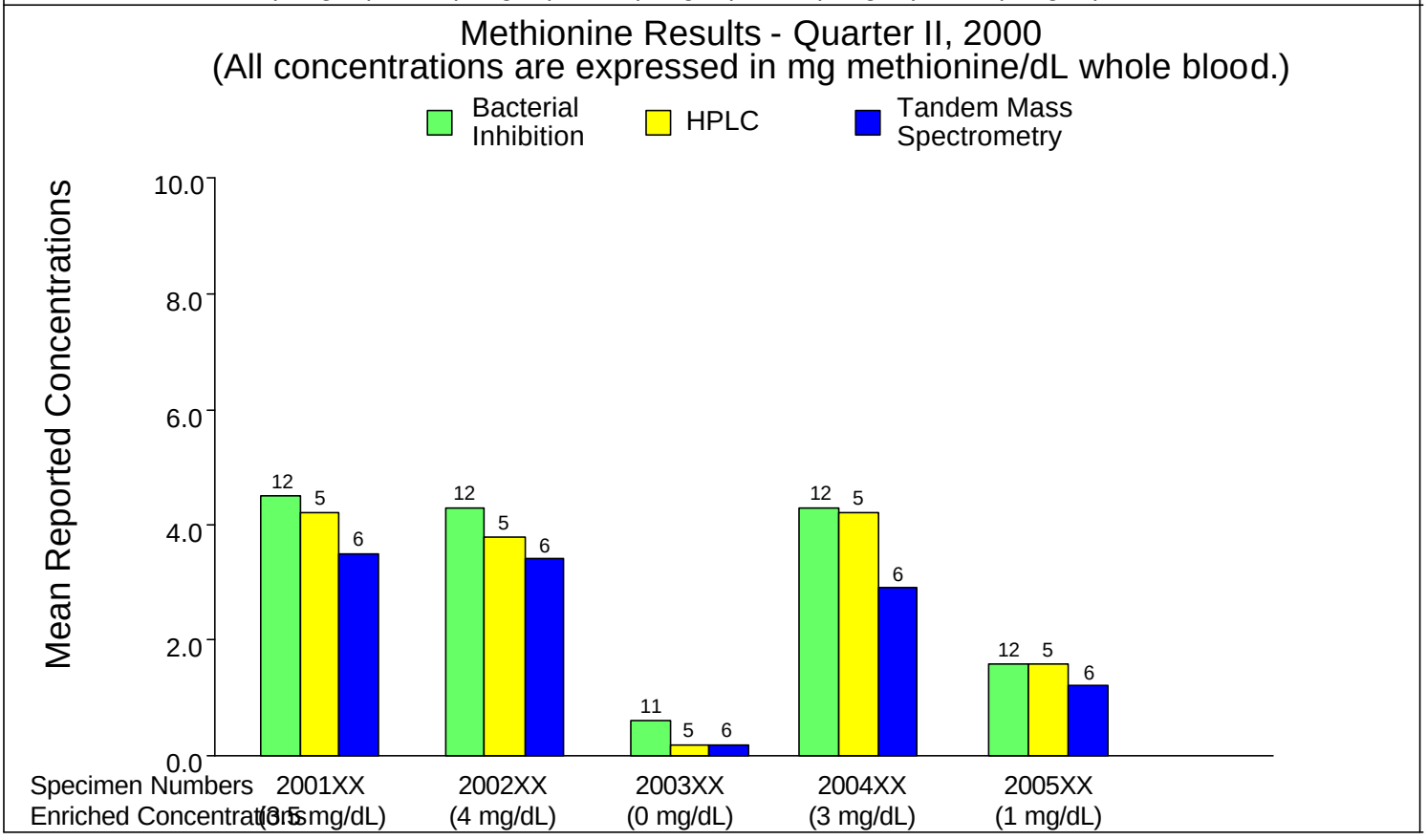

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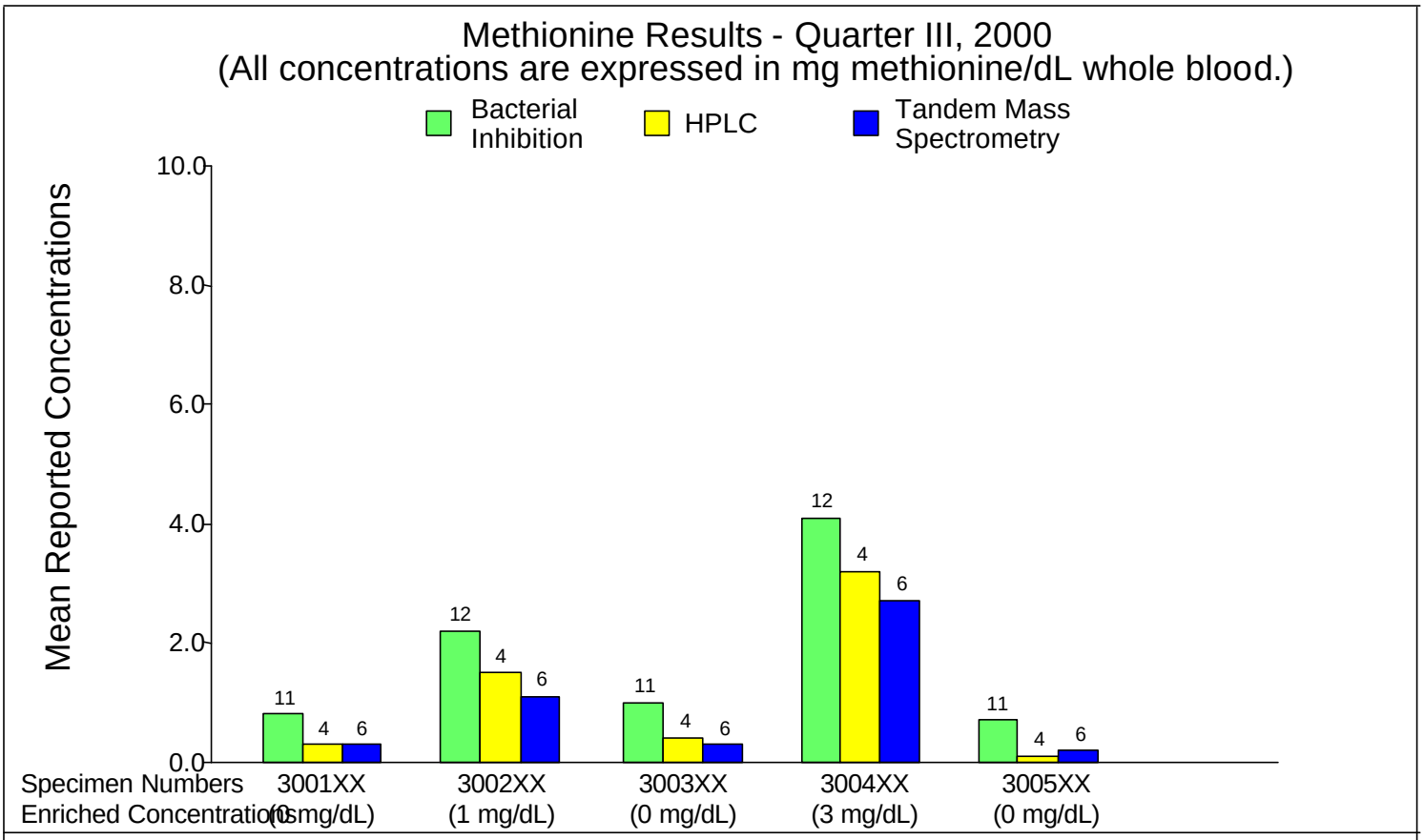

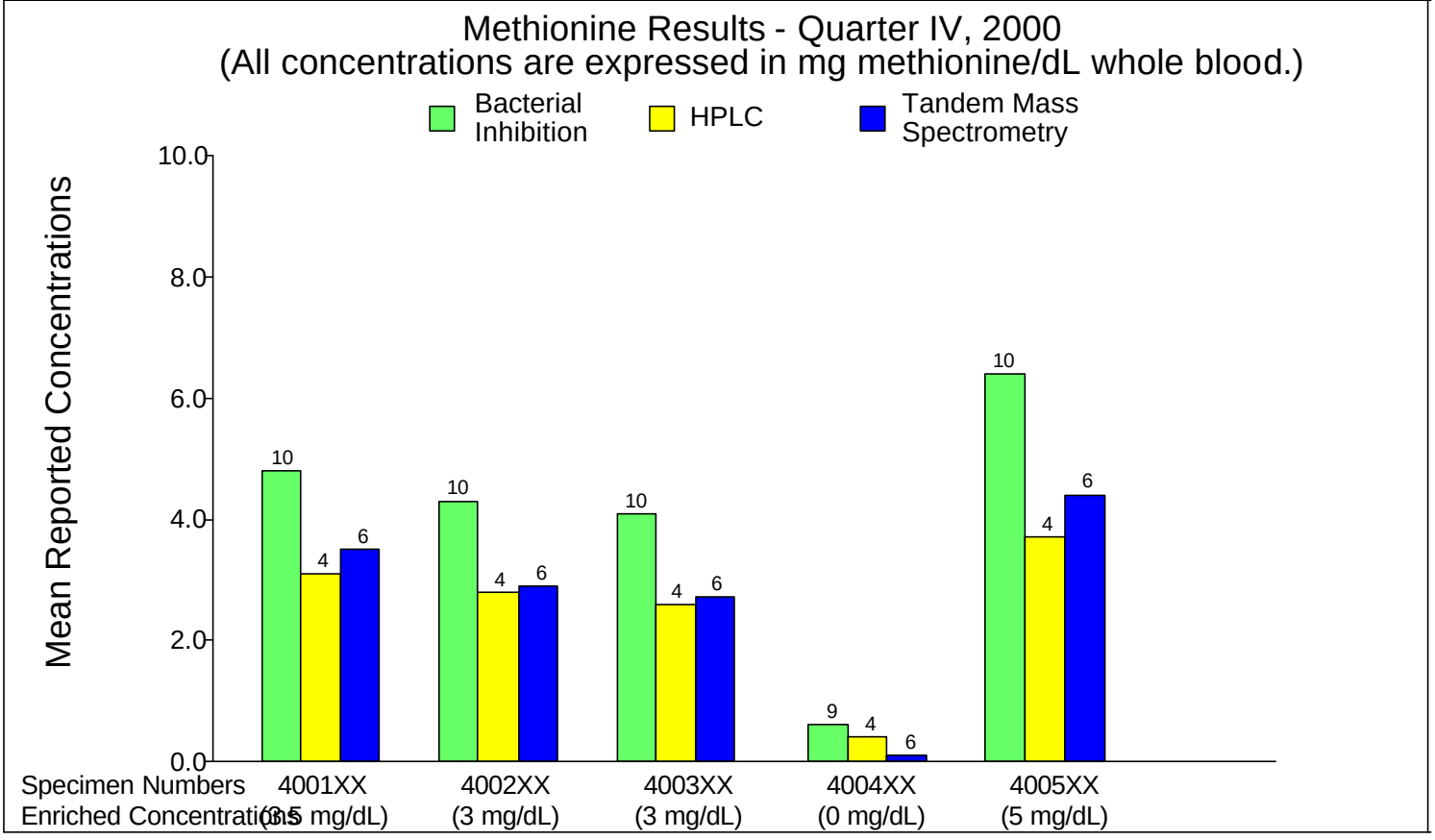

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2000 Performance Evaluation Data

Hypothyroidism Qualitative Assessments

55 T_4 Laboratories - 1115 Assayed T_4 Specimens
612 Positive - 280 Negative - 223 Not Evaluated (NE)

119 TSH Laboratories - 2390 Assayed TSH Specimens
1311 Positive - 601 Negative - 478 Not Evaluated (NE)

Transcription Errors	1.3%
False-Positive Misclassifications	1.5%
False-Negative Misclassifications	0.2%
Labs Making Transcription Errors	10
Labs Misclassifying Specimens	9
Labs Correctly Classifying Specimens	110

Phenylketonuria Qualitative Assessments

129 Laboratories - 2585 Assayed Specimens
1294 Positive - 1162 Negative - 129 Not Evaluated (NE)

Transcription Errors	1.4%
False-Positive Misclassifications	0.9%
False-Negative Misclassifications	0.5%
Labs Making Transcription Errors	7
Labs Misclassifying Specimens	11
Labs Correctly Classifying Specimens	115

Galactosemia Qualitative Assessments

53 Laboratories - 1075 Assayed Specimens
433 Positive - 482 Negative - 160 Not Evaluated (NE)

Transcription Errors	0.0%
False-Positive Misclassifications	0.6%
False-Negative Misclassifications	3.0%
Labs Making Transcription Errors	0
Labs Misclassifying Specimens	9
Labs Correctly Classifying Specimens	44

Congenital Adrenal Hyperplasia Qualitative Assessments

47 Laboratories - 950 Assayed Specimens
284 Positive - 332 Negative - 334 Not Evaluated (NE)

Transcription Errors	0.0%
False-Positive Misclassifications	1.8%
False-Negative Misclassifications	1.4%
Labs Making Transcription Errors	0
Labs Misclassifying Specimens	7
Labs Correctly Classifying Specimens	40

Because manufacturers do not routinely analyze patient specimens, their clinical assessments are omitted from these tables.

2000 Performance Evaluation Data

Maple Syrup Urine Disease Qualitative Assessments

28 Laboratories - 575 Assayed Specimens
318 Positive - 257 Negative - 0 Not Evaluated (NE)

Transcription Errors	0.2%
False-Positive Misclassifications	1.0%
False-Negative Misclassifications	1.0%
Labs Making Transcription Errors	1
Labs Misclassifying Specimens	5
Labs Correctly Classifying Specimens	23

Homocystinuria Qualitative Assessments

25 Laboratories - 515 Assayed Specimens
252 Positive - 211 Negative - 52 Not Evaluated (NE)

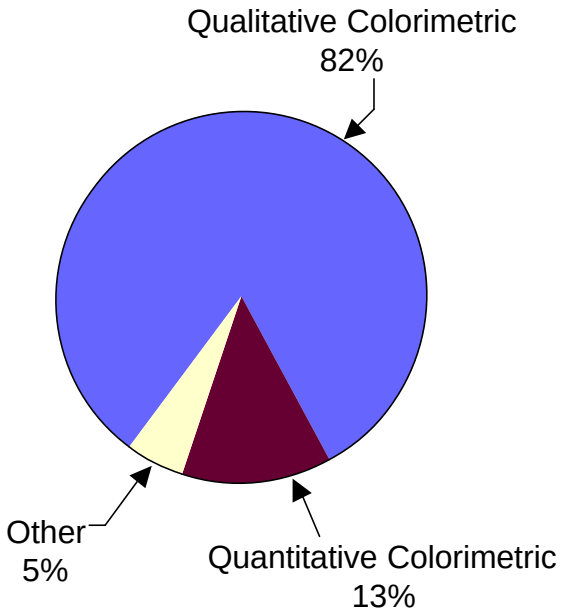
Transcription Errors	0.2%
False-Positive Misclassifications	1.0%
False-Negative Misclassifications	1.0%
Labs Making Transcription Errors	1
Labs Misclassifying Specimens	5
Labs Correctly Classifying Specimens	23

Biotinidase Deficiency Qualitative Assessments

37 Laboratories - 740 Assayed Specimens
300 Positive - 440 Negative

Transcription Errors	0.0%
False-Positive Misclassifications	1.6%
False-Negative Misclassifications	0.7%
Labs Making Transcription Errors	0
Labs Misclassifying Specimens	4
Labs Correctly Classifying Specimens	33

Biotinidase Methods Used By Participants



Because manufacturers do not routinely analyze patient specimens, their clinical assessments are omitted from thes

2000 Performance Evaluation Data

Galactose-1-Phosphate Uridyltransferase Deficiency
Qualitative Assessments
PILOT SURVEYS

57 Laboratories - 1150 Assayed Specimens
289 Positive - 744 Negative - 117 Not Evaluated (NE)

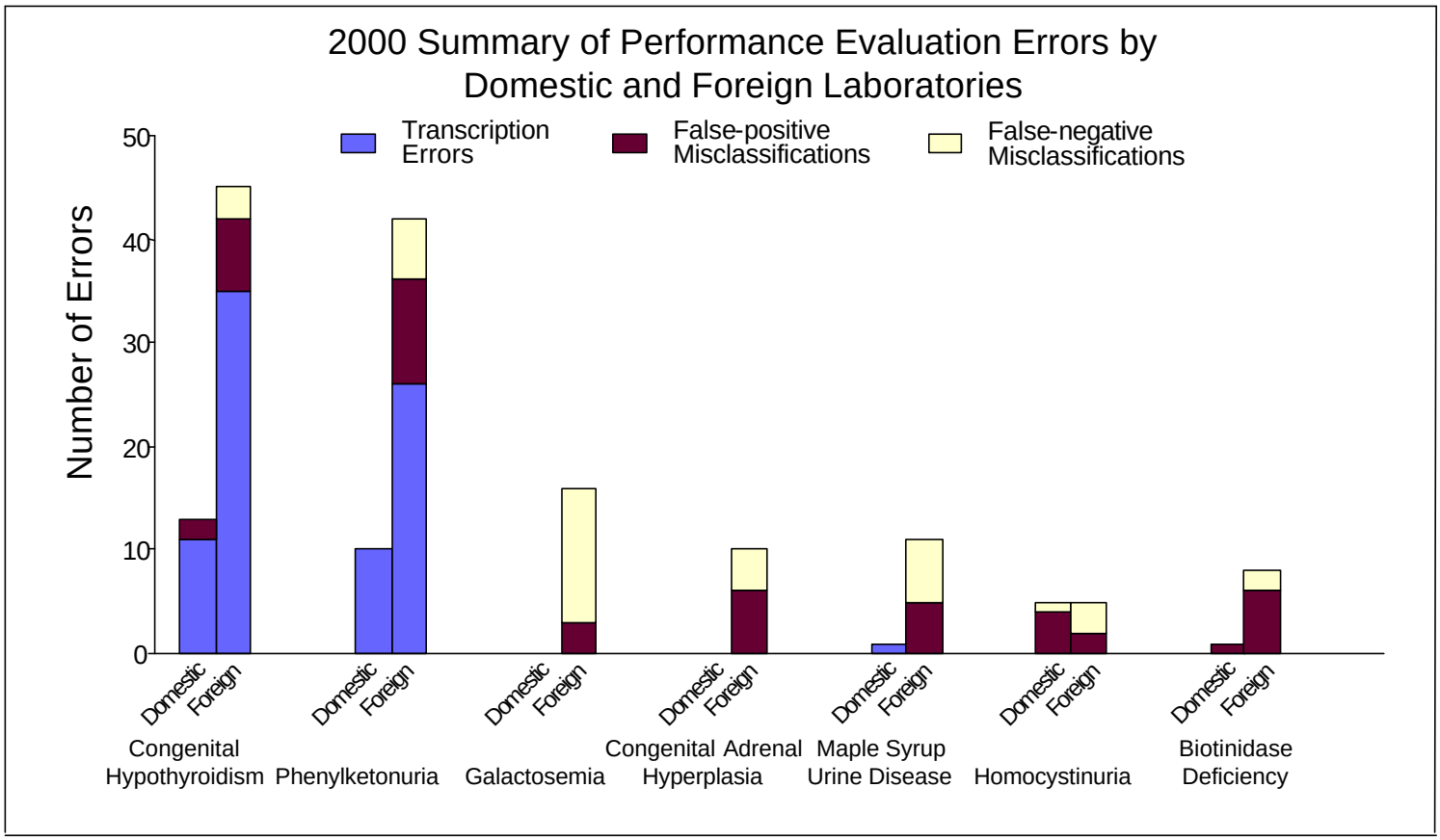
Transcription Errors	1.3%
False-Positive Misclassifications	0.1%
False-Negative Misclassifications	0.3%
Labs Making Transcription Errors	3
Labs Misclassifying Specimens	2
Labs Correctly Classifying Specimens	55

Sickle Cell Disease and Other Hemoglobinopathie
Qualitative Assessments

54 Laboratories - 1090 Assayed Specimens

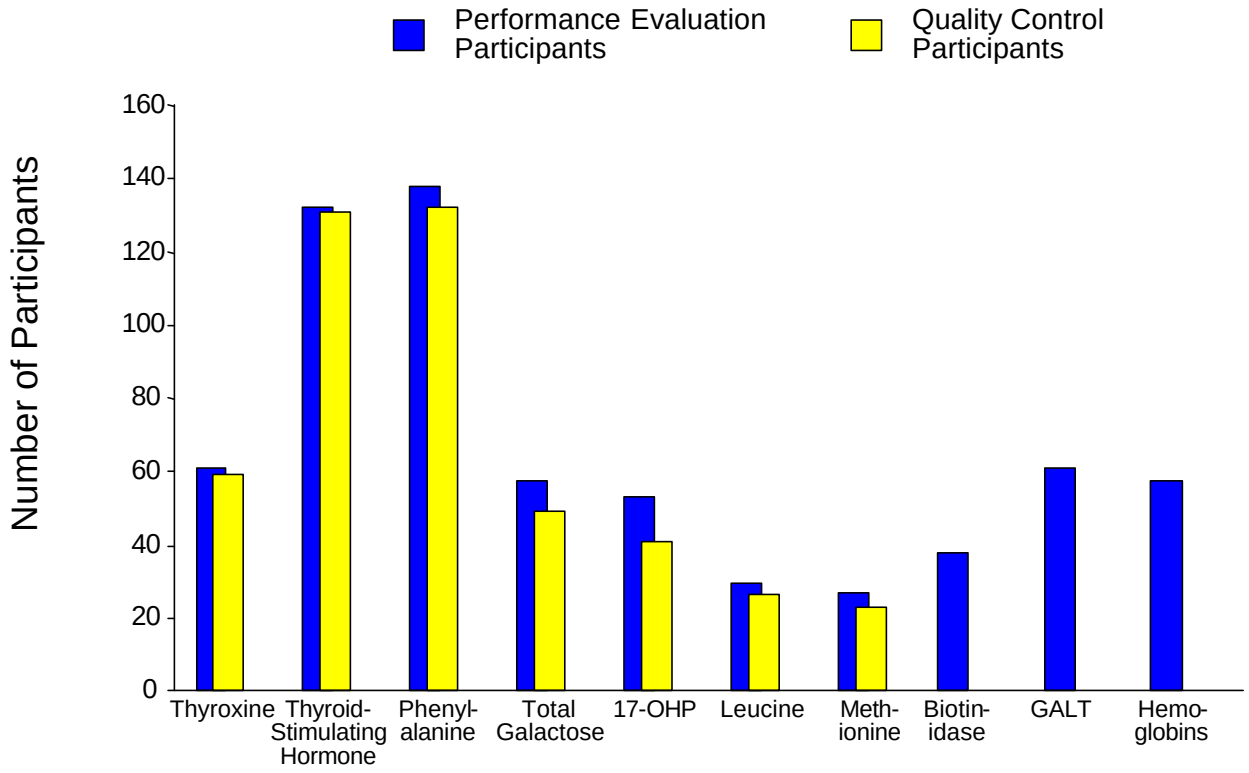
Transcription Errors	1.3%
Phenotype Misclassifications	0.1%
Clinical Assessment Misclassifications	0.3%
Labs Making Transcription Errors	3
Labs Misclassifying Specimens	2
Labs Correctly Classifying Specimens	55

Because manufacturers do not routinely analyze patient specimens, their clinical assessments are omitted from thes



Program Information

Quality Assurance Program Participants for 2000



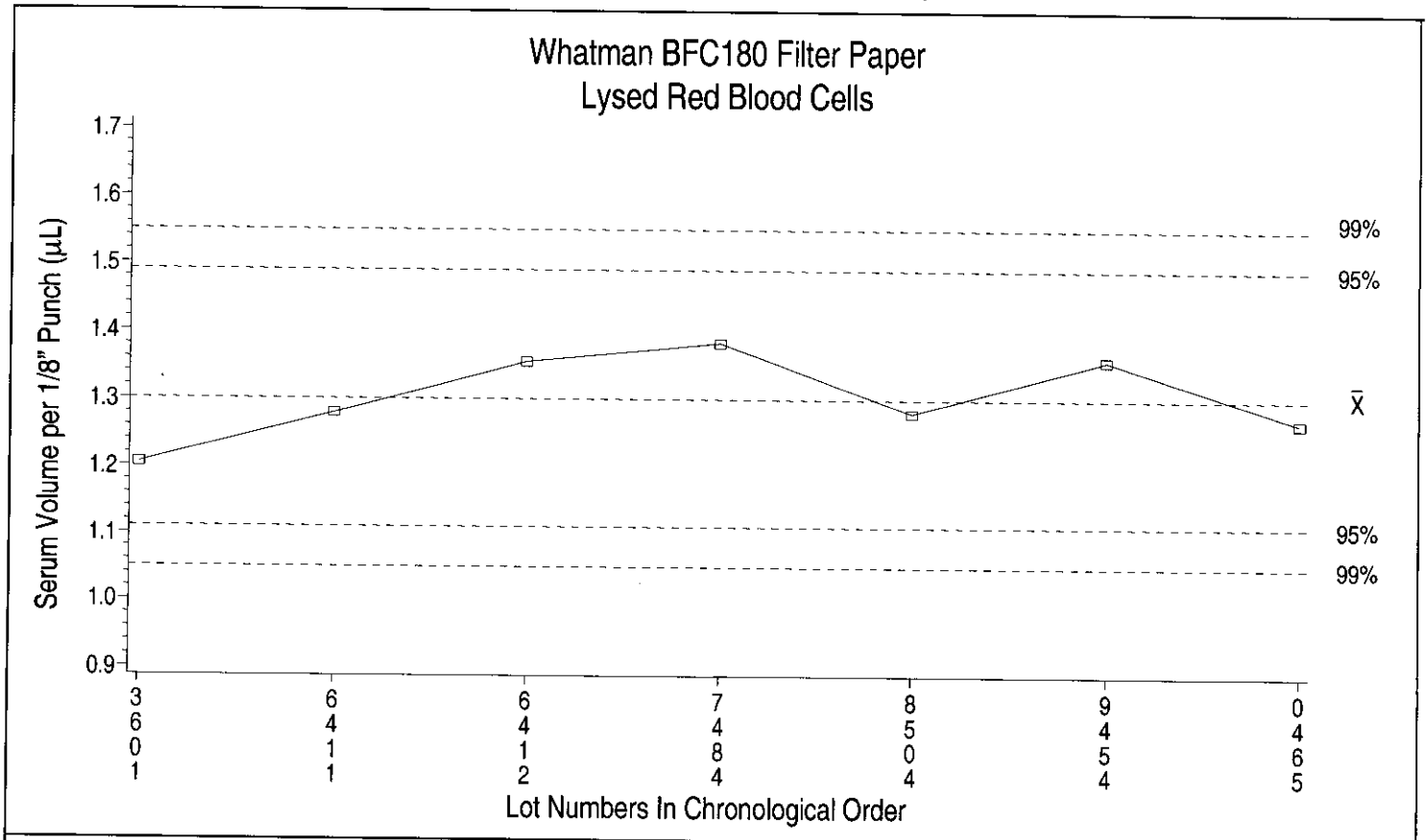
Mean, Minimum, and Maximum Cutoff Values Reported by Domestic and Foreign Laboratories

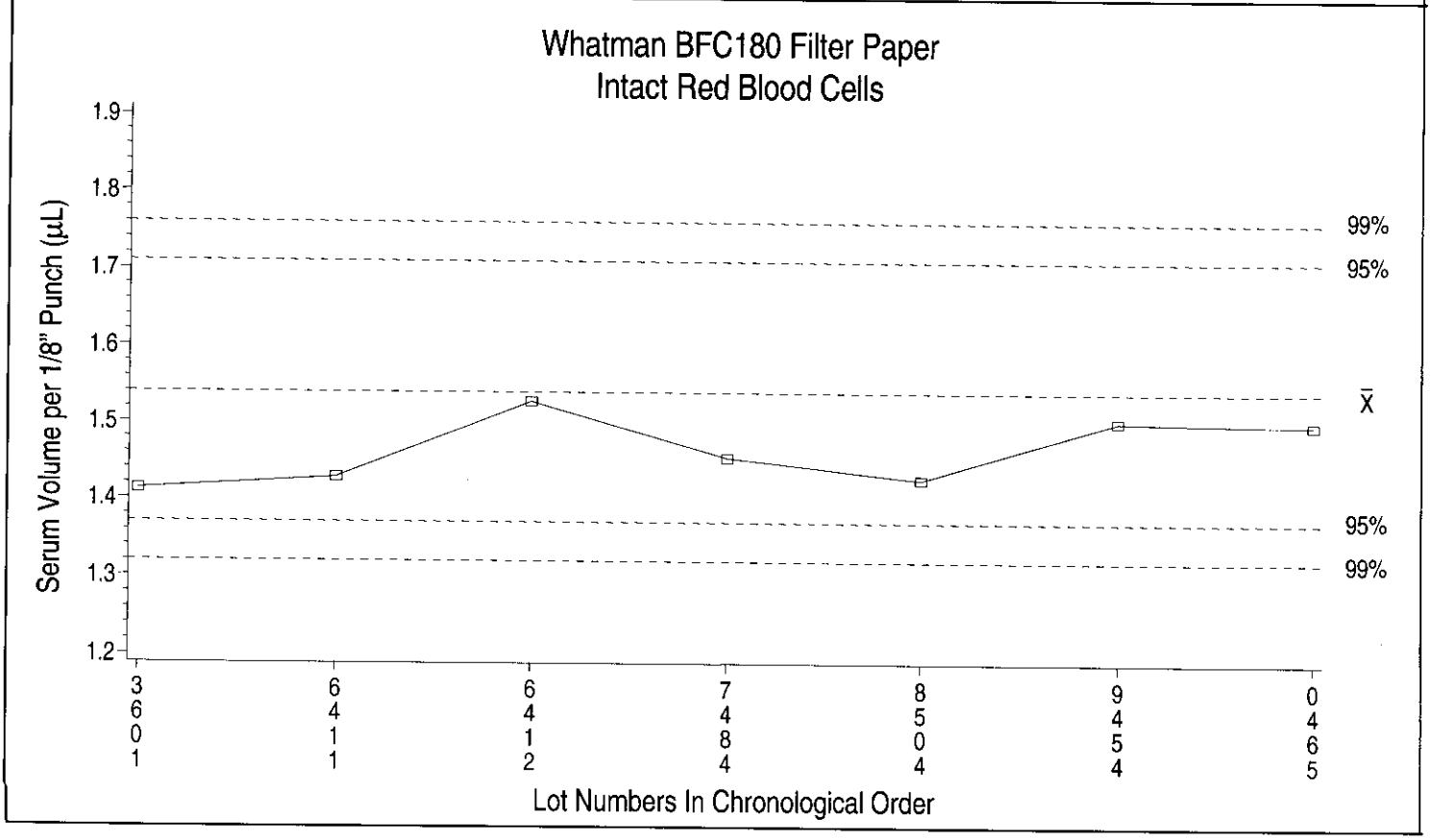
	Domestic			Foreign		
Analyte	N	Mean Cutoff Value*	Min/Max	N	Mean Cutoff Value*	Min/Max
T4	23	6.9	5-13	14	6.9	5-10
TSH	51	29.5	17-50	73	25.8	11-50
Phe	59	3.0	1.5-6	72	3.2	1.3-5.0
Gal	25	9.5	5-20	30	13.0	3.6-27.3
17-OHP	20	46.8	25-65	30	25.3	10-50
Leu	15	3.6	2-5.5	12	4.2	2-7
Met	14	1.6	0.8-3	10	1.9	0.8-4

*Units of measurement for each analyte can be found in the Quality Control section of this report.

Source: Newborn Screening Quality Assurance Program, CDC (October 2000)

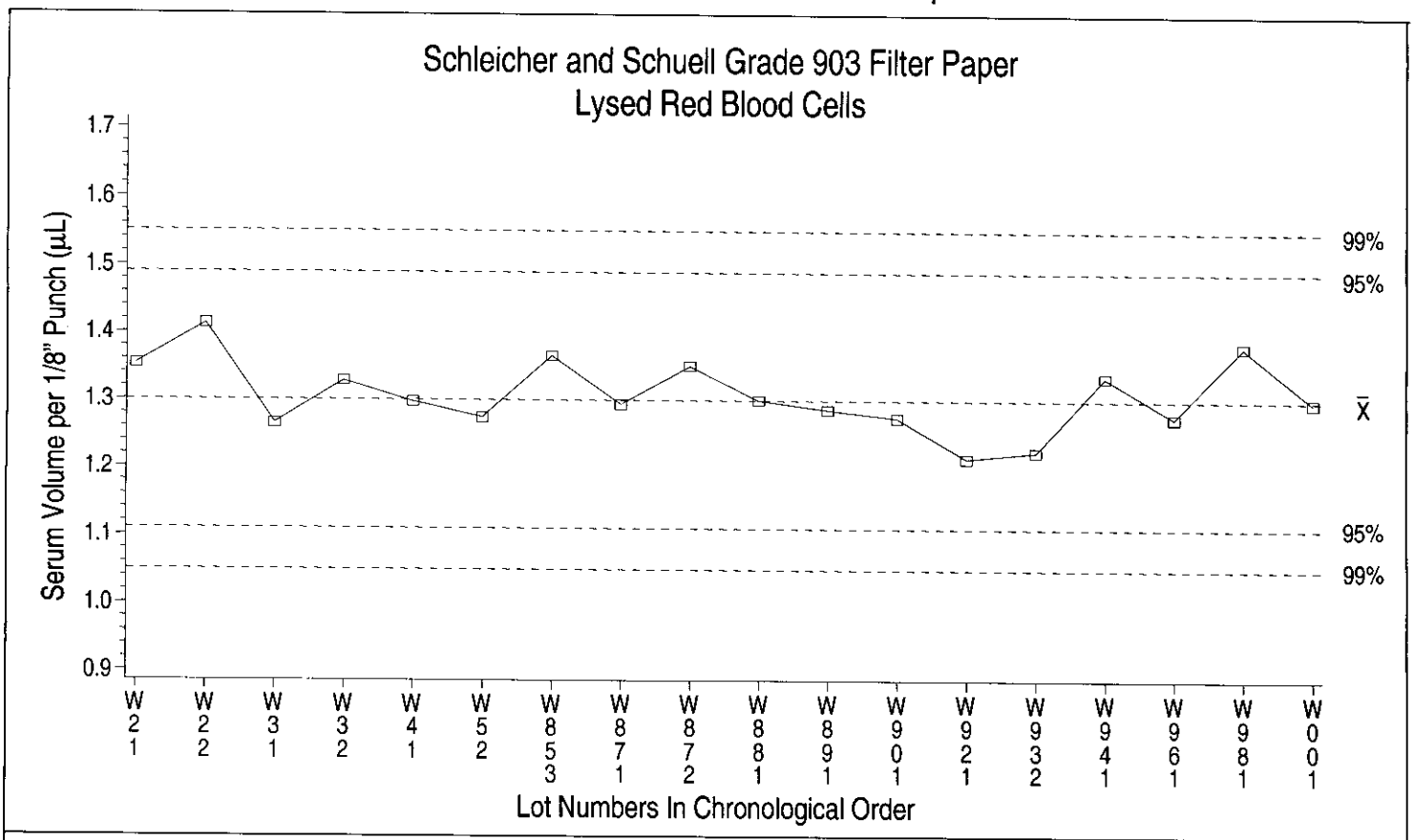
Mean Serum Absorbancies for Production Lots of BFC180 Filter Paper

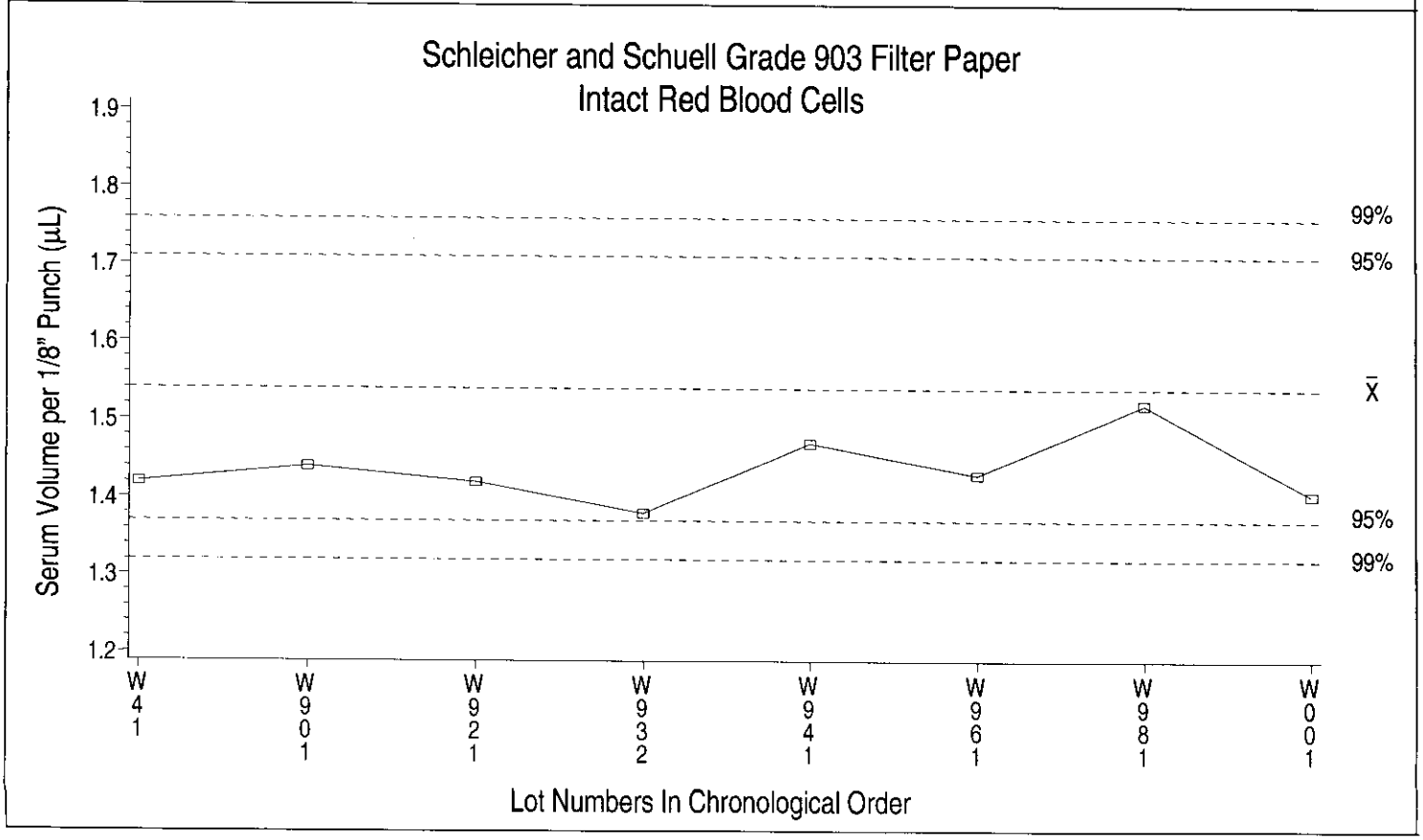




The mean values and confidence intervals (broken lines shown above) are the filter paper evaluation parameters published in the NCCLS Approved Standard (LA4-A3).

Mean Serum Absorbancies for Production Lots of Grade 903 Filter Paper





The mean values and confidence intervals (broken lines shown above) are the filter paper evaluation parameters published in the NCCLS Approved Standard (LA4-A3).

2000 Quality Control Data
Summaries of Statistical Analyses

THYROXINE (µg T_4/dL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 801 - Enriched 2 µg/dL serum						
Diagnostic Products	108	2.4	0.7	1.0	0.4	1.0
ICN Manual	100	2.1	0.5	0.6	0.1	0.9
Neometrics Accuscreen	99	2.9	0.6	0.8	1.4	0.7
Neometrics Neocoat	79	1.8	0.5	0.5	-0.1	0.9
Delfia	226	1.5	0.6	0.7	-0.2	0.8
AutoDelfia	275	1.6	0.6	0.6	-0.3	0.9
Other	116	1.9	0.5	0.6	-0.1	1.0
Lot 802 - Enriched 5.5 µg/dL serum						
Diagnostic Products	109	6.0	0.9	1.5	0.4	1.0
ICN Manual	118	5.1	0.7	0.8	0.1	0.9
Neometrics Accuscreen	100	5.3	0.8	0.9	1.4	0.7
Neometrics Neocoat	78	5.0	0.6	0.6	-0.1	0.9
Delfia	226	4.3	1.0	1.2	-0.2	0.8
AutoDelfia	270	4.3	0.8	1.0	-0.3	0.9
Other	117	5.6	0.8	0.9	-0.1	1.0
Lot 803 - Enriched 8 µg/dL serum						
Diagnostic Products	108	8.4	1.5	2.1	0.4	1.0
ICN Manual	118	7.7	0.9	1.1	0.1	0.9
Neometrics Accuscreen	98	7.1	1.0	1.0	1.4	0.7
Neometrics Neocoat	78	7.5	0.9	0.9	-0.1	0.9
Delfia	225	6.5	1.1	1.2	-0.2	0.8
AutoDelfia	272	6.9	1.3	1.7	-0.3	0.9
Other	119	8.0	1.1	1.2	-0.1	1.0

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

THYROXINE (μg T_4/dL serum)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 901 - Enriched 2 µg/dL serum						
Diagnostic Products	50	2.9	0.8	1.0	1.0	1.0
ICN Manual	50	2.4	0.3	0.6	0.5	0.9
Neometrics Accuscreen	40	2.8	0.4	0.5	0.9	0.9
Neometrics Neocoat	40	2.2	0.4	0.4	0.3	0.9
Delfia	110	1.9	0.5	0.6	0.2	0.8
AutoDelfia	147	1.8	0.4	0.6	-0.1	0.9
Other	68	2.5	0.6	0.7	0.5	1.0
Lot 902 - Enriched 5.5 µg/dL serum						
Diagnostic Products	49	6.7	1.2	1.6	1.0	1.0
ICN Manual	58	5.7	0.6	0.7	0.5	0.9
Neometrics Accuscreen	40	6.1	0.7	0.8	0.9	0.9
Neometrics Neocoat	39	5.3	0.8	0.8	0.3	0.9
Delfia	109	5.0	0.8	0.9	0.2	0.8
AutoDelfia	144	5.0	0.8	1.4	-0.1	0.9
Other	69	6.5	0.9	1.2	0.5	1.0
Lot 903 - Enriched 8 µg/dL serum						
Diagnostic Products	50	9.0	1.4	1.7	1.0	1.0
ICN Manual	59	7.9	0.9	0.9	0.5	0.9
Neometrics Accuscreen	39	8.4	1.0	1.2	0.9	0.9
Neometrics Neocoat	40	7.7	0.8	0.9	0.3	0.9
Delfia	108	7.2	1.0	1.1	0.2	0.8
AutoDelfia	142	7.5	0.8	2.0	-0.1	0.9
Other	68	8.7	0.9	1.0	0.5	1.0

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2000 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (µIU TSH/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 911 - Enriched 25 µIU/mL serum						
Diagnostic Products	98	28.7	3.0	3.5	2.0	1.1
Neometrics Accuscreen	127	25.1	3.5	3.8	-0.1	1.0
Neometrics Accuwell	19	27.6	4.5	7.4	3.2	1.0
ICN Biomedical IRMA	145	28.7	4.0	4.7	2.2	1.0
Delfia	828	25.9	4.0	5.7	-0.6	1.0
AutoDelfia	447	26.0	3.0	4.8	-0.3	1.0
Labsystems hTSH	70	27.3	5.0	6.4	0.3	1.1
In House	126	26.8	5.6	6.5	1.3	1.0
Other	392	25.3	3.5	6.4	-3.0	1.1
Lot 912 - Enriched 40 µIU/mL serum						
Diagnostic Products	98	44.9	4.2	4.8	2.0	1.1
Neometrics Accuscreen	128	38.4	4.5	5.3	-0.1	1.0
Neometrics Accuwell	20	41.0	3.9	4.0	3.2	1.0
ICN Biomedical IRMA	149	42.1	6.1	6.9	2.2	1.0
Delfia	823	40.1	6.0	8.4	-0.6	1.0
AutoDelfia	442	40.7	4.5	7.4	-0.3	1.0
Labsystems hTSH	70	43.7	8.0	9.2	0.3	1.1
In House	128	42.5	6.5	8.6	1.3	1.0
Other	396	40.7	5.8	10.2	-3.0	1.1
Lot 913 - Enriched 80 µIU/mL serum						
Diagnostic Products	100	87.5	9.3	11.2	2.0	1.1
Neometrics Accuscreen	126	78.7	8.9	9.6	-0.1	1.0
Neometrics Accuwell	20	80.1	7.7	16.5	3.2	1.0
ICN Biomedical IRMA	145	84.6	12.7	15.0	2.2	1.0
Delfia	823	82.6	11.9	15.9	-0.6	1.0
AutoDelfia	435	83.0	11.4	14.9	-0.3	1.0
Labsystems hTSH	70	86.9	7.4	11.9	0.3	1.1
In House	127	83.2	12.0	21.2	1.3	1.0
Other	382	86.0	13.4	21.3	-3.0	1.1

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

THYROID-STIMULATING HORMONE (µIU TSH/mL serum)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 011 - Enriched 25 µIU/mL serum						
Diagnostic Products	49	25.2	2.7	3.3	-3.0	1.1
Neometrics Accuscreen	60	21.4	3.4	4.3	-3.3	0.9
Neometrics Accuwell	19	23.5	3.6	3.6	0.2	0.9
ICN Biomedical IRMA	69	29.3	3.4	4.6	0.0	1.1
Delfia	442	24.4	4.0	6.0	-1.0	1.0
AutoDelfia	244	24.9	2.8	4.8	-2.2	1.1
Labsystems hTSH	30	23.9	2.3	3.3	-3.9	1.1
In House	60	25.7	3.7	4.7	1.0	1.0
Other	215	24.1	3.5	6.1	-2.6	1.0
Lot 012 - Enriched 40 µIU/mL serum						
Diagnostic Products	48	38.3	4.2	5.3	-3.0	1.1
Neometrics Accuscreen	60	31.4	4.4	5.9	-3.3	0.9
Neometrics Accuwell	20	34.0	7.1	7.1	0.2	0.9
ICN Biomedical IRMA	67	44.6	4.7	6.6	0.0	1.1
Delfia	445	39.5	5.7	9.4	-1.0	1.0
AutoDelfia	244	39.7	4.5	7.7	-2.2	1.1
Labsystems hTSH	30	39.4	4.4	8.1	-3.9	1.1
In House	59	42.0	4.8	7.7	1.0	1.0
Other	214	38.4	5.8	11.0	-2.6	1.0
Lot 013 - Enriched 80 µIU/mL serum						
Diagnostic Products	49	83.8	8.0	8.1	-3.0	1.1
Neometrics Accuscreen	60	71.3	7.9	9.9	-3.3	0.9
Neometrics Accuwell	20	71.3	10.6	10.6	0.2	0.9
ICN Biomedical IRMA	67	91.6	8.6	17.3	0.0	1.1
Delfia	444	80.1	11.4	18.2	-1.0	1.0
AutoDelfia	245	83.1	8.6	13.7	-2.2	1.1
Labsystems hTSH	30	83.9	8.9	13.5	-3.9	1.1
In House	58	81.3	10.5	17.3	1.0	1.0
Other	216	81.3	10.5	19.8	-2.6	1.0

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2000 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE (mg Phe/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 921- Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition	170	1.6	0.3	0.8	1.5	0.9
HPLC	58	1.4	0.2	0.2	1.4	1.0
Colorimetric	89	2.2	0.3	0.4	1.9	1.1
PerkinElmer (Wallac)	204	1.1	0.2	0.4	1.1	0.8
Fluorometric Manual	60	1.7	0.3	0.6	1.6	1.2
Fluor Cont Flo, In-house	59	2.1	0.2	0.3	2.0	1.1
Fluor Cont Flo, Kit	90	2.0	0.2	0.4	1.9	1.1
Tandem Mass Spec	39	1.6	0.2	0.4	1.6	1.0
Neometrics Accuwell	50	1.8	0.3	0.4	1.6	1.1
Quantase	119	1.9	0.3	0.4	1.7	1.1
Other	60	1.9	0.4	0.8	1.9	0.9
Lot 922 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition	197	4.3	0.7	1.2	1.5	0.9
HPLC	57	4.5	0.4	0.5	1.4	1.0
Colorimetric	90	5.1	0.5	0.9	1.9	1.1
PerkinElmer (Wallac)	203	3.7	0.5	0.8	1.1	0.8
Fluorometric Manual	60	5.4	0.8	1.2	1.6	1.2
Fluor Cont Flo, In-house	60	5.6	0.4	1.0	2.0	1.1
Fluor Cont Flo, Kit	89	5.3	0.4	0.7	1.9	1.1
Tandem Mass Spec	37	4.5	0.3	0.7	1.6	1.0
Neometrics Accuwell	50	4.8	0.4	0.5	1.6	1.1
Quantase	120	4.9	0.6	1.0	1.7	1.1
Other	78	4.6	0.7	1.5	1.9	0.9
Lot 923 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition	196	7.6	0.9	1.6	1.5	0.9
HPLC	60	8.3	0.6	1.2	1.4	1.0
Colorimetric	89	8.9	0.7	1.2	1.9	1.1
PerkinElmer (Wallac)	203	6.8	0.7	1.2	1.1	0.8
Fluorometric Manual	59	10.0	1.3	1.7	1.6	1.2
Fluor Cont Flo, In-house	60	9.7	0.7	1.6	2.0	1.1
Fluor Cont Flo, Kit	90	9.5	0.8	1.5	1.9	1.1
Tandem Mass Spec	38	8.4	0.6	1.0	1.6	1.0
Neometrics Accuwell	50	8.9	0.7	0.9	1.6	1.1
Quantase	119	8.6	1.2	1.9	1.7	1.1
Other	67	8.3	1.0	1.9	1.9	0.9

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 924 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition	196	11.6	1.5	2.8	1.5	0.9
HPLC	60	12.5	0.7	1.5	1.4	1.0
Colorimetric	80	14.4	1.0	2.2	1.9	1.1
PerkinElmer (Wallac)	203	10.6	0.9	1.7	1.1	0.8
Fluorometric Manual	60	15.4	1.7	2.2	1.6	1.2
Fluor Cont Flo, In-house	59	14.9	1.0	2.6	2.0	1.1
Fluor Cont Flo, Kit	90	14.3	1.0	2.0	1.9	1.1
Tandem Mass Spec	38	12.5	0.9	1.8	1.6	1.0
Neometrics Accuwell	50	13.6	1.1	1.2	1.6	1.1
Quantase	118	13.7	1.7	2.8	1.7	1.1
Other	76	11.8	1.3	2.7	1.9	0.9
Lot 021 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition	424	1.6	0.4	0.7	1.7	0.9
HPLC	128	1.3	0.1	0.2	1.3	1.0
Colorimetric	208	2.1	0.3	0.5	2.3	1.4
PerkinElmer (Wallac)	428	1.1	0.2	0.4	1.1	1.0
Fluorometric Manual	159	1.5	0.3	0.6	1.5	1.2
Fluor Cont Flo, In-house	100	1.9	0.2	0.3	1.9	1.3
Fluor Cont Flo, Kit	208	1.8	0.3	0.4	1.8	1.1
Tandem Mass Spec	107	1.3	0.2	0.3	1.3	1.0
Neometrics Accuwell	98	1.7	0.3	0.3	1.8	1.2
Quantase	211	1.9	0.5	1.1	2.1	1.2
Other	128	1.7	0.3	0.6	1.8	1.0
Lot 022 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition	462	4.6	0.8	1.2	1.7	0.9
HPLC	129	4.4	0.3	0.4	1.3	1.0
Colorimetric	207	6.5	0.6	0.9	2.3	1.4
(PerkinElmer (Wallac)	428	4.0	0.4	0.7	1.1	1.0
Fluorometric Manual	159	5.0	1.0	1.3	1.5	1.2
Fluor Cont Flo, In-house	96	5.9	0.5	1.0	1.9	1.3
Fluor Cont Flo, Kit	207	5.3	0.5	0.8	1.8	1.1
Tandem Mass Spec	109	4.3	0.5	0.7	1.3	1.0
Neometrics Accuwell	99	5.5	0.3	0.4	1.8	1.2
Quantase	214	5.9	0.8	1.2	2.1	1.2
Other	158	4.7	0.6	0.9	1.8	1.0

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 023 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition	468	8.2	1.3	1.6	1.7	0.9
HPLC	128	8.3	0.6	1.0	1.3	1.0
Colorimetric	211	12.0	1.8	1.0	2.3	1.4
PerkinElmer (Wallac)	435	7.8	0.7	1.3	1.1	1.0
Fluorometric Manual	160	9.9	1.2	1.8	1.5	1.2
Fluor Cont Flo, In-house	99	10.6	0.9	2.1	1.9	1.3
Fluor Cont Flo, Kit	207	9.8	0.9	1.5	1.8	1.1
Tandem Mass Spec	108	8.4	0.8	1.4	1.3	1.0
Neometrics Accuwell	99	10.4	0.7	0.7	1.8	1.2
Quantase	218	11.0	1.4	2.3	2.1	1.2
Other	138	9.1	0.8	1.5	1.8	1.0
Lot 024 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition	441	12.0	1.7	2.5	1.7	0.9
HPLC	127	12.5	0.9	1.5	1.3	1.0
Colorimetric	198	16.9	1.1	2.1	2.3	1.4
PerkinElmer (Wallac)	430	11.6	1.2	1.9	1.1	1.0
Fluorometric Manual	158	14.3	1.6	2.5	1.5	1.2
Fluor Cont Flo, In-house	100	16.1	1.3	3.2	1.9	1.3
Fluor Cont Flo, Kit	209	14.4	1.2	2.1	1.8	1.1
Tandem Mass Spec	107	12.4	1.8	2.3	1.3	1.0
Neometrics Accuwell	99	15.0	1.0	1.1	1.8	1.2
Quantase	219	15.5	1.9	3.1	2.1	1.2
Other	153	12.4	1.5	2.6	1.8	1.0
Lot 041 - Enriched 0 mg/dL whole blood						
Bacterial Inhibition	216	1.7	0.4	0.9	1.9	0.9
HPLC	79	1.4	0.1	0.1	1.4	1.0
Colorimetric	97	2.2	0.3	0.6	2.6	1.3
PerkinElmer (Wallac)	223	1.3	0.3	0.5	1.3	1.0
Fluorometric Manual	80	1.5	0.4	0.6	1.5	1.2
Fluor Cont Flo, In-house	40	2.1	0.2	0.3	2.2	1.4
Fluor Cont Flo, Kit	130	1.9	0.2	0.4	2.0	1.1
Tandem Mass Spec	69	1.3	0.2	0.5	1.3	1.0
Neometrics Accuwell	50	1.9	0.3	0.3	2.0	1.2
Quantase	120	2.1	0.4	0.5	2.3	1.2
Other	49	2.0	0.4	0.7	1.8	1.0

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 042 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition	239	4.8	0.9	1.3	1.9	0.9
HPLC	80	4.4	0.3	0.4	1.4	1.0
Colorimetric	99	6.6	0.6	1.0	2.6	1.3
PerkinElmer (Wallac)	223	4.3	0.5	0.8	1.3	1.0
Fluorometric Manual	78	5.0	0.9	1.0	1.5	1.2
Fluor Cont Flo, In-house	40	6.6	0.4	0.4	2.2	1.4
Fluor Cont Flo, Kit	127	5.4	0.4	0.9	2.0	1.1
Tandem Mass Spec	70	4.2	0.5	0.7	1.3	1.0
Neometrics Accuwell	50	5.6	0.4	0.4	2.0	1.2
Quantase	118	6.0	0.7	1.0	2.3	1.2
Other	69	4.5	0.5	0.9	1.8	1.0
Lot 043 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition	234	8.5	1.3	1.9	1.9	0.9
HPLC	78	8.4	0.6	1.1	1.4	1.0
Colorimetric	98	12.2	0.8	1.7	2.6	1.3
PerkinElmer (Wallac)	226	8.2	1.0	1.5	1.3	1.0
Fluorometric Manual	80	9.7	1.5	1.8	1.5	1.2
Fluor Cont Flo, In-house	40	12.1	0.7	1.2	2.2	1.4
Fluor Cont Flo, Kit	129	9.8	0.9	1.6	2.0	1.1
Tandem Mass Spec	70	8.4	0.8	1.1	1.3	1.0
Neometrics Accuwell	50	10.6	0.7	0.8	2.0	1.2
Quantase	118	11.2	1.3	2.1	2.3	1.2
Other	59	9.0	0.9	1.2	1.8	1.0
Lot 044 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition	234	11.8	1.7	2.7	1.9	0.9
HPLC	80	12.4	0.9	1.6	1.4	1.0
Colorimetric	98	15.9	1.2	2.5	2.6	1.3
PerkinElmer (Wallac)	225	12.0	1.1	1.7	1.3	1.0
Fluorometric Manual	78	14.4	1.6	2.3	1.5	1.2
Fluor Cont Flo, In-house	38	17.4	0.9	1.4	2.2	1.4
Fluor Cont Flo, Kit	129	14.2	1.1	2.1	2.0	1.1
Tandem Mass Spec	68	12.0	1.4	1.7	1.3	1.0
Neometrics Accuwell	50	15.0	1.0	1.2	2.0	1.2
Quantase	118	15.3	1.5	3.3	2.3	1.2
Other	66	12.8	1.6	3.2	1.8	1.0

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2000 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 921 - Enriched 5 mg/dL whole blood						
Colorimetric	39	6.0	0.9	1.2	0.3	1.2
PerkinElmer (Wallac)	88	6.9	1.9	2.0	3.7	0.8
Fluorometric Manual	130	5.0	0.8	2.4	0.2	1.0
Fluor Cont Flo, Kit	39	5.7	0.5	0.5	1.6	0.9
Neometrics Accuwell	39	6.9	0.6	0.6	2.7	1.0
Quantase	39	6.8	1.1	1.4	-0.5	1.4
Other	50	5.4	0.5	1.2	-0.1	1.1
Lot 922 - Enriched 10 mg/dL whole blood						
Colorimetric	40	12.1	1.3	2.8	0.3	1.2
PerkinElmer (Wallac)	89	12.1	0.9	1.2	3.7	0.8
Fluorometric Manual	127	10.1	1.1	2.3	0.2	1.0
Fluor Cont Flo, Kit	40	11.1	0.6	0.8	1.6	0.9
Neometrics Accuwell	40	12.7	0.9	1.2	2.7	1.0
Quantase	40	12.8	2.1	2.9	-0.5	1.4
Other	48	11.3	2.1	2.3	-0.1	1.1
Lot 923 - Enriched 15 mg/dL whole blood						
Colorimetric	40	18.1	2.0	4.1	0.3	1.2
PerkinElmer (Wallac)	89	16.2	1.1	1.6	3.7	0.8
Fluorometric Manual	125	15.3	1.4	2.9	0.2	1.0
Fluor Cont Flo, Kit	40	16.4	1.0	1.1	1.6	0.9
Neometrics Accuwell	40	18.3	1.2	1.7	2.7	1.0
Quantase	40	20.7	3.1	4.4	-0.5	1.4
Other	50	17.2	4.2	4.3	-0.1	1.1

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 924 - Enriched 30 mg/dL whole blood						
Colorimetric	40	35.4	4.4	6.3	0.3	1.2
PerkinElmer (Wallac)	88	27.1	1.8	2.2	3.7	0.8
Fluorometric Manual	124	29.8	3.0	4.6	0.2	1.0
Fluor Cont Flo, Kit	40	29.6	1.7	1.8	1.6	0.9
Neometrics Accuwell	40	31.7	3.1	4.8	2.7	1.0
Quantase	39	41.4	9.7	12.8	-0.5	1.4
Other	49	33.8	2.2	4.1	-0.1	1.1
Lot 021 - Enriched 5 mg/dL whole blood						
Colorimetric	90	6.1	0.8	2.2	-0.5	1.2
PerkinElmer (Wallac)	187	7.0	0.8	1.1	2.0	0.9
Fluorometric Manual	230	5.7	1.0	2.5	0.5	1.0
Fluor Cont Flo, Kit	108	6.6	0.5	0.8	1.3	1.1
Neometrics Accuwell	79	7.8	0.7	0.8	1.1	1.3
Quantase	80	7.6	1.2	1.4	-2.0	1.8
Other	80	6.3	1.2	1.7	-0.4	1.3
Lot 022 - Enriched 10 mg/dL whole blood						
Colorimetric	90	11.7	1.2	3.9	-0.5	1.2
PerkinElmer (Wallac)	185	11.2	1.1	1.2	2.0	0.9
Fluorometric Manual	237	10.8	1.3	2.2	0.5	1.0
Fluor Cont Flo, Kit	108	12.2	0.9	1.1	1.3	1.1
Neometrics Accuwell	79	13.4	0.9	1.0	1.1	1.3
Quantase	78	16.4	4.2	7.1	-2.0	1.8
Other	79	12.2	2.4	2.7	-0.4	1.3

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 023 - Enriched 15 mg/dL whole blood						
Colorimetric	80	17.6	1.7	6.9	-0.5	1.2
PerkinElmer (Wallac)	189	16.0	1.3	1.7	2.0	0.9
Fluorometric Manual	233	15.6	1.6	2.8	0.5	1.0
Fluor Cont Flo, Kit	108	17.3	1.1	1.5	1.3	1.1
Neometrics Accuwell	79	19.5	1.5	1.6	1.1	1.3
Quantase	78	24.2	5.3	7.3	-2.0	1.8
Other	80	18.8	3.2	5.0	-0.4	1.3
Lot 024 - Enriched 30 mg/dL whole blood						
Colorimetric	80	36.8	4.3	14.7	-0.5	1.2
PerkinElmer (Wallac)	186	30.4	2.8	3.0	2.0	0.9
Fluorometric Manual	235	31.2	2.9	4.9	0.5	1.0
Fluor Cont Flo, Kit	109	33.6	2.6	3.6	1.3	1.1
Neometrics Accuwell	79	38.8	2.9	3.2	1.1	1.3
Quantase	79	52.9	8.3	10.1	-2.0	1.8
Other	80	38.2	4.8	6.6	-0.4	1.3
Lot 041 - Enriched 5 mg/dL whole blood						
Colorimetric	50	5.2	0.9	2.3	-0.5	1.1
PerkinElmer (Wallac)	78	6.6	0.8	1.2	2.3	0.9
Fluorometric Manual	99	5.8	0.7	1.9	0.6	1.0
Fluor Cont Flo, Kit	69	6.8	0.4	1.0	1.7	1.0
Neometrics Accuwell	40	7.3	0.6	0.7	1.5	1.1
Quantase	57	7.5	1.8	2.8	1.0	1.4
Other	30	5.8	0.5	2.0	-1.5	1.3

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 042 - Enriched 10 mg/dL whole blood						
Colorimetric	50	10.3	1.1	4.2	-0.5	1.1
PerkinElmer (Wallac)	78	11.2	1.1	1.4	2.3	0.9
Fluorometric Manual	104	10.3	1.0	2.0	0.6	1.0
Fluor Cont Flo, Kit	68	11.6	0.8	1.4	1.7	1.0
Neometrics Accuwell	38	12.7	0.8	1.0	1.5	1.1
Quantase	60	14.5	2.1	4.6	1.0	1.4
Other	30	11.5	1.3	2.7	-1.5	1.3
Lot 043 - Enriched 15 mg/dL whole blood						
Colorimetric	49	15.9	1.8	7.7	-0.5	1.1
PerkinElmer (Wallac)	79	15.6	1.2	1.7	2.3	0.9
Fluorometric Manual	107	14.9	1.6	2.9	0.6	1.0
Fluor Cont Flo, Kit	69	16.6	1.1	1.9	1.7	1.0
Neometrics Accuwell	39	18.8	1.4	1.7	1.5	1.1
Quantase	60	22.0	3.4	6.6	1.0	1.4
Other	30	17.8	2.8	4.8	-1.5	1.3
Lot 044 - Enriched 30 mg/dL whole blood						
Colorimetric	50	32.6	4.9	13.5	-0.5	1.1
PerkinElmer (Wallac)	79	28.8	2.1	2.7	2.3	0.9
Fluorometric Manual	107	30.3	2.3	5.1	0.6	1.0
Fluor Cont Flo, Kit	69	31.8	2.1	3.3	1.7	1.0
Neometrics Accuwell	39	35.9	3.1	3.1	1.5	1.1
Quantase	60	41.6	6.4	10.2	1.0	1.4
Other	30	38.7	5.4	8.9	-1.5	1.3

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2000 Quality Control Data
Summaries of Statistical Analyses

LEUCINE (mg Leu/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 921 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	87	1.8	0.4	0.6	1.8	0.8
HPLC	38	2.0	0.3	0.3	2.0	0.9
Tandem Mass Spec	30	2.8	0.1	0.9	2.7	1.0
Other	20	2.7	0.5	0.8	2.4	0.9
Lot 922 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	100	4.5	0.8	1.1	1.8	0.8
HPLC	39	4.9	0.5	0.6	2.0	0.9
Tandem Mass Spec	30	5.7	0.3	1.4	2.7	1.0
Other	20	4.7	0.6	0.6	2.4	0.9
Lot 923 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	97	7.4	1.2	1.6	1.8	0.8
HPLC	40	7.9	0.6	0.7	2.0	0.9
Tandem Mass Spec	30	9.5	0.7	2.1	2.7	1.0
Other	20	8.3	1.2	1.2	2.4	0.9
Lot 924 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	100	11.1	1.9	2.5	1.8	0.8
HPLC	40	11.7	0.6	0.9	2.0	0.9
Tandem Mass Spec	30	13.5	0.9	2.9	2.7	1.0
Other	20	12.2	1.3	1.4	2.4	0.9

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

LEUCINE (mg Leu/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 021 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	145	1.8	0.5	0.7	1.7	0.8
HPLC	76	1.7	0.2	0.3	1.7	1.0
Tandem Mass Spec	70	2.5	0.3	0.6	2.5	1.0
Other	49	2.5	0.4	0.7	2.6	0.7
Lot 022 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	158	4.2	0.7	1.3	1.7	0.8
HPLC	75	4.7	0.4	1.4	1.7	1.0
Tandem Mass Spec	70	5.6	0.6	1.4	2.5	1.0
Other	49	4.9	0.6	0.8	2.6	0.7
Lot 023 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	160	7.5	1.0	1.5	1.7	0.8
HPLC	77	8.4	0.6	2.1	1.7	1.0
Tandem Mass Spec	70	9.6	0.7	1.8	2.5	1.0
Other	49	7.9	1.0	1.0	2.6	0.7
Lot 024 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	157	10.9	1.9	2.6	1.7	0.8
HPLC	78	12.5	0.9	3.2	1.7	1.0
Tandem Mass Spec	70	14.0	1.4	2.8	2.5	1.0
Other	49	10.7	1.0	1.1	2.6	0.7

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

LEUCINE (mg Leu/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 041 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	65	1.9	0.5	0.8	1.9	0.8
HPLC	40	2.0	0.1	0.2	2.0	1.1
Tandem Mass Spec	40	2.7	0.4	0.7	2.7	1.1
Other	30	2.8	0.5	0.8	2.9	0.7
Lot 042 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	68	4.4	0.8	1.3	1.9	0.8
HPLC	39	5.3	0.4	1.4	2.0	1.1
Tandem Mass Spec	40	5.7	0.7	1.4	2.7	1.1
Other	30	5.2	0.7	0.8	2.9	0.7
Lot 043 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	68	7.7	0.8	1.7	1.9	0.8
HPLC	39	9.3	0.9	2.6	2.0	1.1
Tandem Mass Spec	40	10.4	1.0	2.4	2.7	1.1
Other	30	8.3	0.8	0.9	2.9	0.7
Lot 044 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	70	11.2	1.5	2.2	1.9	0.8
HPLC	40	13.9	0.7	4.2	2.0	1.1
Tandem Mass Spec	40	14.4	1.5	3.6	2.7	1.1
Other	30	10.6	0.8	1.2	2.9	0.7

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2000 Quality Control Data
Summaries of Statistical Analyses

METHIONINE (mg Met/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 921 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	70	0.4	0.2	0.4	0.3	1.1
HPLC	40	0.3	0.1	0.1	0.2	0.8
Tandem Mass Spec	30	0.5	0.1	0.3	0.4	0.8
Lot 922 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition Assays	76	1.3	0.4	0.6	0.3	1.1
HPLC	39	0.9	0.1	0.2	0.2	0.8
Tandem Mass Spec	30	1.2	0.1	0.2	0.4	0.8
Lot 923 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	89	3.9	0.7	1.4	0.3	1.1
HPLC	40	2.4	0.2	0.3	0.2	0.8
Tandem Mass Spec	30	3.0	0.2	0.4	0.4	0.8
Lot 924 - Enriched 6 mg/dL whole blood						
Bacterial Inhibition Assays	87	7.2	1.3	2.3	0.3	1.1
HPLC	40	4.7	0.3	0.5	0.2	0.8
Tandem Mass Spec	30	5.5	0.3	0.7	0.4	0.8

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

METHIONINE (mg Met/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 021 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	148	0.5	0.2	0.4	0.5	1.2
HPLC	69	0.3	0.1	0.2	0.4	0.9
Tandem Mass Spec	78	0.3	0.1	0.2	0.3	0.9
Lot 022 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition Assays	167	1.6	0.4	0.6	0.5	1.2
HPLC	68	1.3	0.3	0.7	0.4	0.9
Tandem Mass Spec	82	1.3	0.4	0.6	0.3	0.9
Lot 023 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	175	3.9	0.9	1.3	0.5	1.2
HPLC	67	3.1	0.4	1.4	0.4	0.9
Tandem Mass Spec	69	3.1	0.2	0.3	0.3	0.9
Lot 024 - Enriched 6 mg/dL whole blood						
Bacterial Inhibition Assays	180	7.5	1.5	2.3	0.5	1.2
HPLC	65	5.8	0.8	2.4	0.4	0.9
Tandem Mass Spec	79	6.0	0.7	0.8	0.3	0.9

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

METHIONINE (mg Met/dL whole blood)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 041 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	68	0.5	0.2	0.4	0.6	1.1
HPLC	30	0.5	0.1	0.3	0.5	1.0
Tandem Mass Spec	50	0.3	0.1	0.2	0.4	0.9
Lot 042 - Enriched 1 mg/dL whole blood						
Bacterial Inhibition Assays	78	1.8	0.7	0.9	0.6	1.1
HPLC	30	1.4	0.3	0.7	0.5	1.0
Tandem Mass Spec	49	1.3	0.2	0.2	0.4	0.9
Lot 043 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	78	3.9	0.7	1.3	0.6	1.1
HPLC	30	3.6	0.4	1.7	0.5	1.0
Tandem Mass Spec	50	3.3	0.3	0.5	0.4	0.9
Lot 044 - Enriched 6 mg/dL whole blood						
Bacterial Inhibition Assays	80	7.3	1.3	2.0	0.6	1.1
HPLC	30	6.5	0.5	3.2	0.5	1.0
Tandem Mass Spec	49	5.8	0.6	0.8	0.4	0.9

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2000 Quality Control Data
Summaries of Statistical Analyses

17 ∝-HYDROXYPROGESTERONE (ng 17-OHP/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 654 - Enriched 25 ng/mL serum						
Neometrics	49	27.5	1.7	1.9	8.6	0.8
Delfia	100	28.7	2.7	4.0	-1.1	1.2
AutoDelfia	107	28.9	2.5	6.3	1.3	1.1
In House	10	35.8	4.8	4.8	10.9	1.1
Other	20	25.3	3.3	3.5	7.5	0.8
Lot 655 - Enriched 50 ng/mL serum						
Neometrics	48	47.6	3.0	3.1	8.6	0.8
Delfia	98	55.9	5.6	8.7	-1.1	1.2
AutoDelfia	106	56.7	4.6	11.8	1.3	1.1
In House	10	67.7	6.2	6.2	10.9	1.1
Other	20	49.5	5.2	5.2	7.5	0.8
Lot 656 - Enriched 100 ng/mL serum						
Neometrics	48	85.2	8.2	8.8	8.6	0.8
Delfia	99	115.5	14.7	23.6	-1.1	1.2
AutoDelfia	110	112.1	11.2	28.4	1.3	1.1
In House	10	117.5	10.9	10.9	10.9	1.1
Other	20	85.2	5.0	12.5	7.5	0.8

* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

17 ∝-HYDROXYPROGESTERONE (ng 17-OHP/mL serum)
- Continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y-Intercept*	Slope
Lot 657 - Enriched 25 ng/mL serum						
Neometrics	108	26.5	3.2	3.3	7.9	0.8
Delfia	186	29.3	4.5	5.5	1.9	1.1
AutoDelfia	250	28.4	3.7	6.3	1.6	1.1
In House	30	31.8	4.9	4.9	7.2	1.0
Other	89	26.1	3.0	3.9	5.4	0.9
Lot 658 - Enriched 50 ng/mL serum						
Neometrics	107	46.1	5.6	7.0	7.9	0.8
Delfia	189	56.5	6.7	8.5	1.9	1.1
AutoDelfia	248	54.7	7.0	12.5	1.6	1.1
In House	29	57.9	7.4	8.3	7.2	1.0
Other	90	50.7	5.5	6.3	5.4	0.9
Lot 659 - Enriched 100 ng/mL serum						
Neometrics	107	83.3	11.8	15.1	7.9	0.8
Delfia	188	111.3	17.3	23.1	1.9	1.1
AutoDelfia	248	108.2	14.8	30.2	1.6	1.1
In House	30	107.1	15.0	21.0	7.2	1.0
Other	88	92.1	10.1	12.1	5.4	0.9

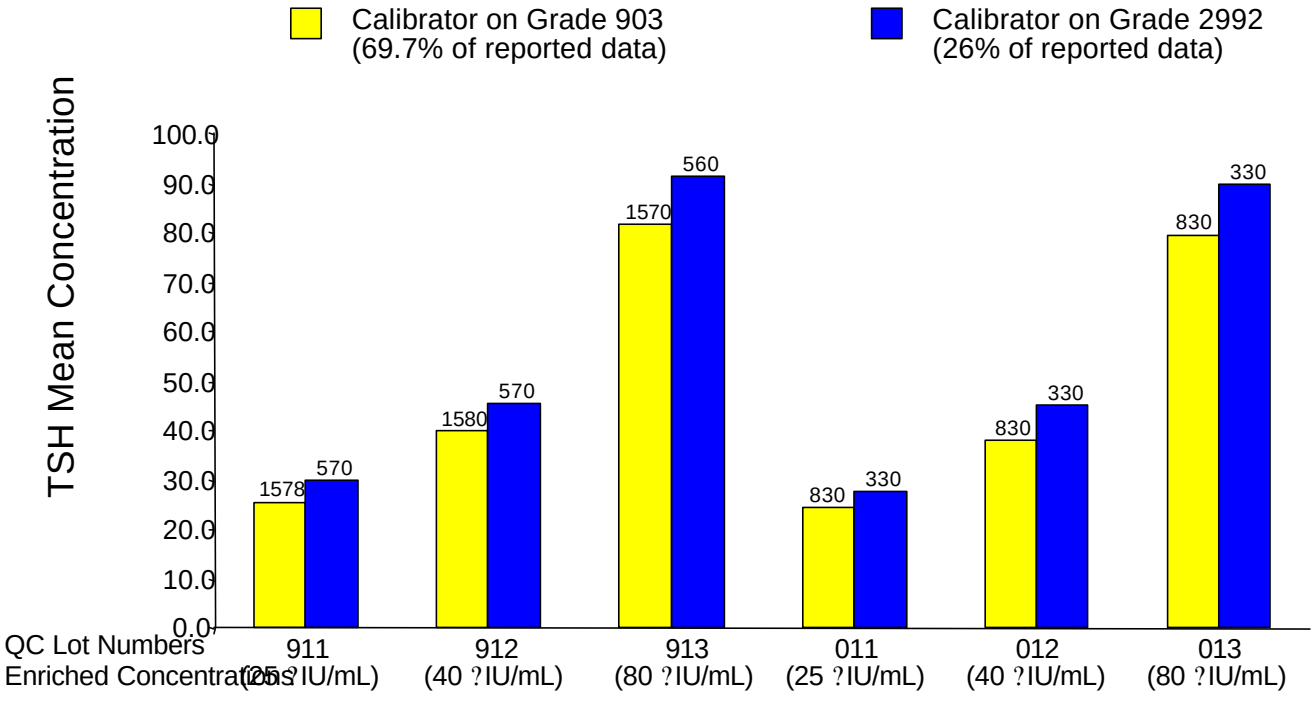
* Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

Program Information

Percentages of QC Data Reported Using Different Calibrator Matrices

Analyte	DBS S&S 903(%)	DBS S&S 2992 (%)	DBS Whatman (%)	Aqueous Calib/Stds (%)	Serum, Blood Calib/Stds (%)	Other Liquid (%)
T4	94.8	5.2	0	0	0	0
TSH	69.7	26.0	1.4	1.7	1.2	0
Phe	63.0	20.0	2.3	12.3	0.1	2.3
Gal	71.2	11.3	4.5	11.9	0	1.1
17-OHP	75.3	24.7	0	0	0	0
Leu	70.3	7.8	0	21.9	0	0
Met	67.7	9.2	0	23.1	0	0

TSH Mean Concentrations When Using Calibrators on Schleicher & Schuell Grades 903 and 2992 Filter Papers



The numbers of specimens assayed (includes all methods) are shown above the bars.
CDC QCs are prepared on S&S Grade 903 filter paper.

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director
Jeffrey P. Koplan, M.D., M.P.H.
Director
National Center for Environmental Health
Richard J. Jackson, M.D., M.P.H.
Director
Division of Laboratory Sciences
Eric J. Sampson, Ph.D.
Chief
Clinical Biochemistry Branch
Newborn Screening Quality Assurance Program
W. Harry Hannon, Ph.D.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Contributors:
Barbara W. Adam
Carol Bell
Paul Dantonio
Marie C. Earley, Ph.D.
F. Hugh Gardner
L. Omar Henderson, Ph.D.
Roberta Jensen
Timothy Lim, Ph.D
Joanne Mei, Ph.D.
Nancy Meredith
Carrie Young

Production:
Connie Singleton
Sarah Brown

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
WASHINGTON, DC 20036-3320

President
Ronald Cada Dr. Ph.
Chairman, Newborn Screening Committee
Ann Willey, Ph.D.

PHL

INQUIRIES TO:

Carol Bell, Editor • Centers for Disease Control and Prevention (CDC)
Newborn Screening Quality Assurance Program • Mailstop F-43
4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: CBell@cdc.gov